STRENGTH IN NUMBERS

HOW INDEPENDENT PRACTICES CAN THRIVE BY WORKING TOGETHER

TECHNOLOGY
New rules around patient access

CHRONIC CONDITIONS
Managing patients with migraines

CAREERS
Eliminating the gender pay gap for physicians
**FASENRA** is indicated as an add-on maintenance treatment of patients 12 years and older with severe eosinophilic asthma. **FASENRA** is not indicated for treatment of other eosinophilic conditions or for the relief of acute bronchospasm or status asthmaticus.

**What could reducing exacerbations mean for your severe asthma patients?**

**TO FIND OUT...**

**TEST** for elevated blood eosinophils (≥150 cells/µL)*1,2 with a simple blood test (CBC with differential).3,4

**TARGET** eosinophils directly with **FASENRA**, a biologic that provides near complete depletion of eosinophils in 24 hours.†5-7

The mechanism of action and the relationship between the pharmacological properties and clinical efficacy has not been established.

**TREAT** with **FASENRA** for the POWER TO HELP PREVENT EXACERBATIONS and reduce oral corticosteroid use.5,6-10

**HELP YOUR PATIENTS**

**TAKE CONTROL OF THEIR ASTHMA**

SCAN HERE TO LEARN MORE & SEE IF **FASENRA** IS APPROPRIATE FOR YOUR PATIENT

www.FASENRAOPTIONS.com

*Although not defined by clinical guidelines, one characterization of eosinophilic asthma can be a blood eosinophil count of ≥150 cells/µL.1,2*

†The pharmacodynamic response (blood eosinophil depletion) following repeat subcutaneous (SC) dosing was evaluated in asthma patients on adjacent pages.

**IMPORTANT SAFETY INFORMATION**

**CONTRAINDICATIONS**

Known hypersensitivity to benralizumab or excipients.

**WARNINGS AND PRECAUTIONS**

**Hypersensitivity Reactions**

Hypersensitivity reactions (e.g., anaphylaxis, angioedema, urticaria, rash) have occurred after administration of FASENRA. These reactions generally occur within hours of administration, but in some instances have a delayed onset (e.g., days). Discontinue in the event of a hypersensitivity reaction. Please see additional Important Safety Information on next page and Brief Summary of full Prescribing Information on adjacent pages.
IMPORTANT SAFETY INFORMATION (cont’d)

WARNINGS AND PRECAUTIONS (cont’d)

Acute Asthma Symptoms or Deteriorating Disease
FASENRA should not be used to treat acute asthma symptoms, acute exacerbations, or acute bronchospasm.

Reduction of Corticosteroid Dosage
Do not discontinue systemic or inhaled corticosteroids abruptly upon initiation of therapy with FASENRA. Reductions in corticosteroid dose, if appropriate, should be gradual and performed under the direct supervision of a physician. Reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy.

Parasitic (Helminth) Infection
It is unknown if FASENRA will influence a patient’s response against helminth infections. Treat patients with pre-existing helminth infections before initiating therapy with FASENRA. If patients become infected while receiving FASENRA and do not respond to anti-helminth treatment, discontinue FASENRA until infection resolves.

ADVERSE REACTIONS
The most common adverse reactions (incidence ≥ 5%) include headache and pharyngitis. Injection site reactions (eg, pain, erythema, pruritus, papule) occurred at a rate of 2.2% in patients treated with FASENRA compared with 1.9% in patients treated with placebo.

USE IN SPECIFIC POPULATIONS
A pregnancy exposure registry monitors pregnancy outcomes in women exposed to FASENRA during pregnancy. To enroll call 1-877-311-8972 or visit www.motherhtobaby.org/fasenra.

The data on pregnancy exposure from the clinical trials are insufficient to inform on drug-associated risk. Monoclonal antibodies such as benralizumab are transported across the placenta during the third trimester of pregnancy; therefore, potential effects on a fetus are likely to be greater during the third trimester of pregnancy.

INDICATION
FASENRA is indicated for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.

- FASENRA is not indicated for treatment of other eosinophilic conditions
- FASENRA is not indicated for the relief of acute bronchospasm or status asthmaticus

PLEASE SEE BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION ON ADJACENT PAGE.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch or call 1-800-FDA-1088.

STUDY DESIGNS

SIROCCO AND CALIMA (Trials 1 and 2)
SIROCCO (48-week) and CALIMA (56-week) were 2 randomized, double-blind, parallel-group, placebo-controlled, multicenter studies comparing FASENRA 30 mg SC Q4W for the first 3 doses, then QBW thereafter; benralizumab 30 mg SC Q4W, and placebo SC. A total of 1204 (SIROCCO) and 1306 (CALIMA) patients aged 12-75 years old with severe asthma uncontrolled on high-dose ICS (SIROCCO) and medium- to high-dose ICS (CALIMA) plus LABA with or without additional controllers were included. Patients had a history of ≥2 exacerbations requiring systemic corticosteroids or temporary increase in usual dosing in the previous year. Patients were stratified by geography, age, and blood eosinophil counts (≥300 cells/µL and <300 cells/µL). The primary endpoint was annual exacerbation rate ratio vs placebo in patients with blood eosinophil counts of ≥300 cells/µL on high-dose ICS and LABA. Exacerbations were defined as a worsening of asthma that led to use of systemic corticosteroids for ≥3 days, temporary increase in a stable OCS background dose for ≥3 days, emergency/urgent care visit because of asthma that needed systemic corticosteroids, or inpatient hospital stay of ≥24 hours because of asthma. Key secondary endpoints were prebronchodilator FEV1, and total asthma symptom score at Week 48 (SIROCCO) and Week 56 (CALIMA) in the same population.3,10

ZONDA (Trial 3)
A 28-week, randomized, double-blind, parallel-group, placebo-controlled, multicenter OCS reduction study comparing the efficacy and safety of FASENRA (30 mg SC Q4W) for the first 3 doses, then QBW thereafter; benralizumab (30 mg SC Q4W), and placebo (SC Q4W). A total of 220 adult (18-75 years old) patients with severe asthma on high-dose ICS plus LABA and daily OCS (7.5 to 40 mg/day), blood eosinophil counts of ≥150 cells/µL, and a history of ≥1 exacerbation in the previous year were included. The primary endpoint was the median percent reduction from baseline in the final daily OCS dose while maintaining asthma control.8

REFERENCES
FASENRA® (benralizumab) injection, for subcutaneous use

Initial U.S. Approval: 2017

Brief Summary of Prescribing Information. For complete prescribing information consult official package insert.

INDICATIONS AND USAGE

FASENRA is indicated for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype [see Clinical Studies (14) in the full Prescribing Information].

Limitations of use:
- FASENRA is not indicated for treatment of other eosinophilic conditions.
- FASENRA is not indicated for the relief of acute bronchospasm or status asthmaticus.

DOSEAGE AND ADMINISTRATION

Recommended Dose

FASENRA is for subcutaneous use only.

The recommended dose of FASENRA is 30 mg administered once every 4 weeks for the first 3 doses, and then once every 8 weeks thereafter by subcutaneous injection into the upper arm, thigh, or abdomen.

General Administration Instructions

FASENRA is intended for use under the guidance of a healthcare provider. In line with clinical practice, monitoring of patients after administration of biologic agents is recommended [see Warnings and Precautions (5.1) in the full Prescribing Information].

Administer FASENRA into the thigh or abdomen. The upper arm can also be used if a healthcare provider or caregiver administers the injection. Prior to administration and FASENRA by leaving carton at room temperature for about 30 minutes. Visually inspect FASENRA for particulate matter and discoloration prior to administration. FASENRA is clear to opalescent, colorless to slightly yellow, and may contain a few translucent or white to off-white particles. Do not use FASENRA if the liquid is cloudy, discolored, or if it contains large particles or foreign particulate matter.

Prefilled Syringe

The prefilled syringe is for administration by a healthcare provider.

Autoinjector (FASENRA PEN®)

FASENRA PEN is intended for administration by patients/caregivers. Patients/caregivers may inject after proper training in subcutaneous injection technique, and after the healthcare provider determines it is appropriate.

Instructions for Administration of FASENRA Prefilled Syringe (Healthcare Providers)

Refer to Figure 1 to identify the prefilled syringe components for use in the administration steps.

Figure 1

6. Inject all of the medication by pushing in the plunger all the way until the plunger head is completely between the needle guard activation clips. This is necessary to activate the needle guard.

7. After injection, maintain pressure on the plunger head and remove the needle from the skin. Release pressure on the plunger head to allow the needle guard to cover the needle. Do not re-cap the prefilled syringe.

Do not touch the needle guard activation clips to prevent premature activation of the needle safety guard.

1. Grasp the syringe body, not the plunger, to remove prefilled syringe from the tray. Check the expiration date on the syringe. The syringe may contain small air bubbles; this is normal. Do not expel the air bubbles prior to administration.

2. Do not remove needle cover until ready to inject. Hold the syringe body and remove the needle cover by pulling straight off. Do not hold the plunger or plunger head while removing the needle cover or the plunger may move. If the prefilled syringe is damaged or contaminated (for example, dropped without needle cover in place), discard and use a new prefilled syringe.

3. Gently pinch the skin and insert the needle at the recommended injection site (i.e., upper arm, thigh, or abdomen).

4. Discard the used syringe into a sharps container.

5. Instructions for Administration of FASENRA PEN

Refer to the FASENRA PEN ‘Instructions for Use’ for more detailed instructions on the preparation and administration of FASENRA PEN [See Instructions for Use in the full Prescribing Information]. A patient may self-inject or the patient caregiver may administer FASENRA PEN subcutaneously after the healthcare provider determines it is appropriate.

CONTRAINDICATIONS

FASENRA is contraindicated in patients who have known hypersensitivity to benralizumab or any of its excipients [see Warnings and Precautions (5.1) in the full Prescribing Information].

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Hypersensitivity reactions (e.g., angioedema, urticaria, rash) have occurred following administration of FASENRA. These reactions generally occur within hours of administration, but in some instances have a delayed onset (i.e., days). In the event of a hypersensitivity reaction, FASENRA should be discontinued [see Contraindications (4) in the full Prescribing Information].

Acute Asthma Symptoms or Deteriorating Disease

FASENRA should not be used to treat acute asthma symptoms or acute exacerbations. Do not use FASENRA to treat acute bronchospasm or status asthmaticus. Patients should seek medical advice if their asthma remains uncontrolled or worsens after initiation of treatment with FASENRA.

Reduction of Corticosteroid Dosage

Do not discontinue systemic or inhaled corticosteroids abruptly upon initiation of therapy with FASENRA. Reductions in corticosteroid dose, if appropriate, should be gradual and performed under the direct supervision of a physician. Reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmasking conditions previously suppressed by systemic corticosteroid therapy.

Parasitic (Helminth) Infection

Eosinophils may be involved in the immunological response to some helminth infections. Patients with known helminth infections were excluded from participation in clinical trials. It is unknown if FASENRA will influence a patient’s response against helminth infections. Treat patients with pre-existing helminth infections before initiating therapy with FASENRA. If patients become infected while receiving treatment with FASENRA and do not respond to anti-helminth treatment, discontinue treatment with FASENRA until infection resolves.

ADVERSE REACTIONS

The following adverse reactions are described in greater detail in other sections:
- Hypersensitivity Reactions [see Warnings and Precautions (5.1) in the full Prescribing Information]

Clinical Trials Experience

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

Across Trials 1, 2, and 3, 1,808 patients received at least 1 dose of FASENRA [see Clinical Studies (14) in the full Prescribing Information]. The data described below reflect exposure to FASENRA in 1,863 patients, including 1,556 exposed for at least 24 weeks and 1,387 exposed for at least 48 weeks. The safety exposure for FASENRA is derived from two Phase 3 placebo-controlled studies (Trials 1 and 2) from 48 weeks duration FASENRA every 4 weeks (n=841), FASENRA every 4 weeks for 3 doses, then every 8 weeks thereafter the recommended dose (see Dosage and Administration (2.1) in the full Prescribing Information). The population studied was 12 to 75 years of age, of which 64% were female and 79% were white. Adverse reactions that occurred at greater than or equal to 3% incidence are shown in Table 1. Table 1. Adverse Reactions with FASENRA with Greater than or Equal to 3% Incidence in Patients with Asthma (Trials 1 and 2)

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>FASENRA (N=822)</th>
<th>Placebo (N=847)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>6</td>
<td>8</td>
</tr>
<tr>
<td>Pyrexia</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Pharyngitis*</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Hypersensitivity reactions†</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>

*Pharyngitis was defined by the following terms: Pharyngitis, Pharyngitis bacterial, Viral pharyngitis, Pharyngitis strepoccusal.
† Hypersensitivity Reactions were defined by the following terms: Urticaria, Urticaria papular, and ‘Rash’ [see Warnings and Precautions (5.1) in the full Prescribing Information].
FASENRA® (benralizumab) injection, for subcutaneous use

26-Week Trial
Adverse reactions from Trial 3 with 28 weeks of treatment with FASENRA (n=73) or placebo (n=75) in which the incidence was more common in FASENRA than placebo include headache (8.2% compared to 5.3%, respectively) and pyrexia (2.7% compared to 1.3%, respectively) [see Clinical Studies (14) in the full Prescribing Information]. The frequencies for the remaining adverse reactions with FASENRA were similar to placebo.

Injection site reactions
In Trials 1 and 2, injection site reactions (e.g., pain, erythema, pruriitus, papule) occurred at a rate of 2.2% in patients treated with FASENRA compared with 1.9% in patients treated with placebo.

Immunogenicity
As with all therapeutic proteins, there is potential for immunogenicity. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to benralizumab in the studies described below with the incidence of antibodies in other studies or to other products may be misleading.

Overall, treatment-emergent anti-drug antibody response developed in 13% of patients treated with FASENRA at the recommended dosing regimen during the 48 to 56 week treatment period in 12% of patients treated with FASENRA developed neutralizing antibodies. Anti-benralizumab antibodies were associated with increased clearance of benralizumab and increased blood eosinophil levels in patients with high anti-drug antibody titers compared to antibody negative patients. No evidence of an association of anti-drug antibodies with efficacy or safety was observed.

Postmarketing Experience
In addition to adverse reactions reported from clinical trials, the following adverse reactions have been identified during post approval use of FASENRA. 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 drug exposure. These events have been chosen for inclusion due to their seriousness, frequency of reporting, or causal connection to FASENRA or a combination of these factors.

DRUG INTERACTIONS
No formal drug interaction studies have been conducted.

USE IN SPECIFIC POPULATIONS

Pregnancy
Pregnancy Exposure Registry
There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to FASENRA during pregnancy. Healthcare providers can enroll patients or encourage patients to enroll themselves by calling 1-877-311-8972 or visiting mothertobaby.org/FASENRA.

Risk Summary
The data on pregnancy exposure from the clinical trials are insufficient to inform on drug-associated risk. Monoclonal antibodies such as benralizumab are transported across the placenta during the third trimester of pregnancy; therefore, potential effects on a fetus are likely to be greater during the third trimester of pregnancy. In a prenatal and postnatal development study conducted in cynomolgus monkeys, there was no evidence of fetal harm with IV administration of benralizumab throughout pregnancy at doses that produced exposures up to approximately 310 times the exposure at the maximum recommended human dose (MRHD) of 30 mg SC [see Data].

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

Clinical Considerations

Disease-associated maternal and/or embryo/fetal risk:
In women with poorly or moderately controlled asthma, evidence demonstrates that there is an increased risk of pre-eclampsia in the mother and prematurity, low birth weight, and small for gestational age in the neonate. The level of asthma control should be monitored in pregnant women and treatment adjusted as necessary to maintain optimal control.

Data
Animal Data
In a prenatal and postnatal development study, pregnant cynomolgus monkeys received benralizumab from beginning on GD20 to GD52 (dependent on pregnancy determination), on day 7, and 14 days thereafter throughout the gestation period and 1-month postpartum (maximum 14 doses) at doses that produced exposures up to approximately 310 times that achieved with the MRHD (on an AUC basis with maternal IV doses up to 30 mg/kg once every 2 weeks). Benralizumab did not elicit adverse effects on fetal or neonatal growth (i.e., organ weight function) up to 6.5 months after birth. There was no evidence of treatment-related external, visceral, or skeletal malformations. Benralizumab was not teratogenic in cynomolgus monkeys. Benralizumab crossed the placenta in cynomolgus monkeys. Benralizumab concentrations were approximately equal in mothers and infants on day 7, but were lower in infants at later time points. Eosinophil counts were suppressed in infant monkeys with gradual recovery by 6 months postpartum; however, recovery of eosinophil counts was not observed for one infant monkey during this period.

Lactation

Risk Summary
There is no information regarding the presence of benralizumab in human or animal milk, and the effects of benralizumab on the breast fed infant and on milk production are not known. However, benralizumab is a humanized monoclonal antibody (IgG1κ-class), and immunoglobulin G (IgG) is present in human milk in small amounts. If benralizumab is transferred into human milk, the effects of local exposure in the gastrointestinal tract and potential limited systemic exposure in the infant to benralizumab are unknown. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for benralizumab and any potential adverse effects on the breast-fed child from benralizumab or from the underlying maternal condition.

Pediatric Use
There were 108 adolescents aged 12 to 17 with asthma enrolled in the Phase 3 exacerbation trials (Trial 1: n=53; Trial 2: n=55). Of these, 46 received placebo, 40 received FASENRA every 4 weeks for 3 doses, followed by every 8 weeks thereafter, and 22 received FASENRA every 4 weeks. Patients were required to have a history of 2 or more asthma exacerbations requiring oral or systemic corticosteroid treatment in the past 12 months and reduced lung function at baseline (pre-bronchodilator FEV1<90%) despite regular treatment with medium or high dose ICS and LABA with or without OCS or other controller therapy. The pharmacokinetics of benralizumab in adolescents 12 to 17 years of age were consistent with adults based on population pharmacokinetic analysis and the reduction in blood eosinophil counts was similar to that observed in adults following the same FASENRA treatment. The adverse event profile in adolescents was generally similar to the overall population in the Phase 3 studies [see Adverse Reactions (6.1) in the full Prescribing Information]. The safety and efficacy in patients younger than 12 years of age has not been established.

Geriatric Use
Of the total number of patients in clinical trials of benralizumab, 13% (n=323) were 65 and over, while 0.4% (n=9) were 75 and over. No overall differences in safety or effectiveness were noted between these patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

OVERDOSAGE
Doses up to 200 mg were administered subcutaneously in clinical trials to patients with eosinophilic disease without evidence of dose-related toxicities.

There is no specific treatment for an overdose with benralizumab. If overdose occurs, the patient should be treated supportively with appropriate monitoring as necessary.

PATIENT COUNSELING INFORMATION
Advise the patients and/or caregivers to read the FDA-approved patient labeling (Patient Information and Instructions for Use for FASENRA PEN) before the patient starts using FASENRA and each time the prescription is renewed as there may be new information they need to know.

Provide proper training to patients and/or caregivers on proper subcutaneous injection technique using the FASENRA PEN, including asptic technique, and the preparation and administration of FASENRA PEN prior to use. Advise patients to follow sharps disposal recommendations [see instructions for Use in the full Prescribing Information].

Hypersensitivity Reactions
Inform patients that hypersensitivity reactions (e.g., anaphylaxis, angioedema, urticaria, rash) have occurred after administration of FASENRA. These reactions generally occurred within hours of FASENRA administration, but in some instances had a delayed onset (i.e., days). Instruct patients to contact their healthcare provider if they experience symptoms of anaphylaxis or urticaria. [see Warnings and Precautions (5.2) in the full Prescribing Information].

Not for Acute Symptoms or Deteriorating Disease
Inform patients that FASENRA does not treat acute asthma symptoms or acute exacerbations. Inform patients to seek medical advice if their asthma remains uncontrolled or worsens after initiation of treatment with FASENRA [see Warnings and Precautions (5.2) in the full Prescribing Information].

Reduction of Corticosteroid Dose
Inform patients to not discontinue systemic or inhaled corticosteroids except under the direct supervision of a physician. Inform patients that reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy [see Warnings and Precautions (5.2) in the full Prescribing Information].

Pregnancy Exposure Registry
Inform women there is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to FASENRA during pregnancy and that they can enroll in the Pregnancy Exposure Registry by calling 1-877-311-8972 or by visiting mothertobaby.org/FASENRA [see Use in Specific Populations (8.1) in the full Prescribing Information].

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PHYSICIANS CRAVE INDEPENDENCE AND AUTONOMY. AT THE SAME TIME, IT’S NEVER BEEN MORE CHALLENGING FOR PHYSICIANS TO RETAIN THEIR INDEPENDENCE.

AS HEALTH CARE IN THE UNITED STATES CONSOLIDATES — WITH MANY METROPOLITAN AREAS DOMINATED BY LARGE HOSPITAL SYSTEMS, HOSPITAL-OWNED PRACTICES AND LARGER MEDICAL GROUPS — MANY INDEPENDENT PRACTICES ARE FINDING IT HARDER TO COMPETE, ESPECIALLY AS REGULATIONS AND VALUE-BASED INITIATIVES MAKE IT MORE DIFFICULT FOR PHYSICIAN PRACTICES TO GO THEIR OWN WAY. IN MANY WAYS, THEY ARE SMALL FISH AMONG THE BIGGER FISH IN A BIG POND.

SO WHAT’S AN INDEPENDENT PHYSICIAN TO DO? SELL TO THE HOSPITAL? GO DIRECT PAY OR CONCIERGE? WHILE THOSE ARE OPTIONS — AND THEY MAY BE RIGHT FOR YOU DEPENDING ON YOUR CIRCUMSTANCES — THERE IS ANOTHER OPTION THAT IS GROWING IN POPULARITY.

IF AN INDEPENDENT PRACTICE IS A SMALL FISH, THEN WHY CAN’T A BUNCH OF SMALL FISH BAND TOGETHER TO GAIN SIZE AND STRENGTH?

OUR COVER STORY THIS MONTH FOCUSES ON HOW PHYSICIANS CAN JOIN FORCES TO BETTER COMPETE IN THEIR MARKET FOR PATIENTS, REVENUE, AND MORE. OPTIONS INCLUDE INDEPENDENT PRACTICE ASSOCIATIONS, CLINICALLY INTEGRATED NETWORKS. OUR COVER STORY TAKES A DEEP DIVE INTO THESE, DISCUSSING THE PROS AND CONS WITH PHYSICIANS WHO ARE ALREADY IN THESE GROUPS.

WE HAVE OTHER GREAT CONTENT THIS MONTH, INCLUDING:

- Practical tips on how physicians can address the gender pay gap, which remains a very considerable problem. Female physicians earn considerably less than their male counterparts. Rebekah Bernard, M.D., offers tips on how female physicians can navigate this challenge.


I HOPE YOU ENJOY THE ISSUE. AND, AS ALWAYS, IF YOU HAVE FEEDBACK ON OUR CONTENT, ARTICLE IDEAS, OR WOULD LIKE TO CONTRIBUTE TO MEDICAL ECONOMICS®, PLEASE REACH OUT TO US AT medec@mjhlifesciences.com.

Mike Hennessy Sr.
Chairman and Founder of MJH Life Sciences™

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COVID-19 COVERAGE CENTRAL

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

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

To read all of our ongoing coverage, go to MedicalEconomics.com

Perfect your telehealth program

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

Watch this video and others at: bit.ly/medecvideo

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Have a question for our advisers?  
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How independent practices can survive by working together

by Jeffrey Bendix Senior Editor

Many independent practice owners today are in a difficult bind. By training and temperament, they are fiercely devoted to maintaining their autonomy. But survival in today’s environment requires the financial resources and access to patient data that doctors usually can get only by being part of a hospital system or some other large organization. Moreover, federal antitrust laws prohibit them from working together to obtain more lucrative contracts with payers.

So how can these practices stay in business without sacrificing their independence?

One solution lies in creating, or joining, an independent practice association (IPA) and/or a clinically integrated network (CIN). IPAs provide
practices with many of the clinical support services, technological resources and group purchasing advantages enjoyed by hospital systems and large multispecialty practices while allowing their members to remain independent. Approximately 300,000 physicians are in an IPA, according to the Independent Practice Association of America.

In a CIN, participating practices form an “umbrella” corporate structure — usually a limited liability company (LLC) — under which they aggregate quality and cost data with the goal of demonstrating the network’s ability to provide high-value care. The LLC can use that data to negotiate value-based contracts that apply across its member practices.

Practices that aren’t able to maintain their quality levels can be removed from the network.

Quality and accountability are keys to success

Demonstrating and maintaining quality is key to keeping a CIN on the right side of antitrust laws, explains Allen Dobson, M.D., FAAFP, former president and chief executive officer of Community Care of North Carolina and Medical Economics® editor-in-chief. “If you’re working to enhance quality and hold each other accountable, then the law says a CIN can sign contracts on behalf of all the members and operate as one.”

Guidelines for how independent practices can legally cooperate were laid out in a 1996 joint statement from the Federal Trade Commission and Department of Justice. For example, the statement designates the percentage of specialists in a geographic area that can be included in a physician network (20% for exclusive networks and 30% for nonexclusive) without drawing government scrutiny.

“The guidelines represented the agencies’ compromise between the need to guard against price fixing and desire to allow independent practices to engage in limited forms of cooperation,” says William Maruca, J.D., a health care attorney with the law firm Fox Rothschild in Pittsburgh.

“As a general rule, the antitrust laws create pretty difficult barriers for independent practices to coordinate any relationships with payers,” Maruca adds. “And that hasn’t changed much since 1996.”

Benefits to physicians and payers

Still, if organized properly, a CIN offers benefits to both payers and physicians, Dobson says. “For the payer it means they now they’ve got one signature covering all these small groups and holding them accountable for their costs and quality. And it allows the practices to participate in value-based contracts because now they’ve got scale and technology and support.”

Tom Banning, CEO of the Texas Academy of Family Physicians in Austin, views CINs and IPAs as frameworks within which doctors can work together to prepare for the end of fee-for-service medicine and its replacement by forms of value-based care. He has spent much of the past decade preaching that message, he says, with mixed results.

“Some groups have understood that value-based care was the direction the system was moving and jumped at the opportunity. Others tell me they are waiting for a sign before they pull the trigger. I tell them when they see that sign, it’s an 18-wheeler about to run them over.”

Much of the resistance, he believes, stems from the culture of medicine. “Most doctors have been trained to work in silos, and that’s how they’ve practiced,” he says. “Physicians were expected to be the team leader and do everything, and that sort of thinkinghamstrings their ability to think outside of their proverbial box.”

Antidote to practice consolidation

One physician who has embraced Banning’s message wholeheartedly is Christopher Crow, M.D., CEO and co-founder of Catalyst Health Network, a CIN based in Dallas. Crow, who founded a family practice in 2000, had grown alarmed by the growing consolidation of primary care practices under the umbrellas of the region’s two major hospital systems.

“My practice had grown into a level 3 patient-centered medical home (PCMH), and through my PCMH contract I got to see data showing how much less it costs for independent physicians to care for patients compared to a large health system,” he recalls. “If this consolidation continues, it will send health care costs through the roof, so we’ve got to do something about it.”

Crow met with 30 or so like-minded primary care colleagues and developed the framework for the entity that became Catalyst. They were quickly able to recruit several hundred more, enough to enable Catalyst to enter into value-based contracts with national payers on behalf of its members. The contracts pay physicians on a fee-for-service basis but include opportunities for shared savings, along with monthly per-capita care management fees. The latter, Crow explains, is used to pay for business operation and clinical support services the CIN provides to its participating members, such as revenue cycle management, IT support, care coordinators and pharmacy technicians.
Clinically Integrated Networks 101: Two physicians explain how their CIN works

Collaborative of Long Island. Founded just two years ago, it has grown to include 10 practices and about 50 practitioners. The collaborative entered into several value-based payer contracts, and saved money for its practices by using its group purchasing power, through which group payer group purchasing powers.

To find out more about how CINs can help independent practices, Medical Economics spoke recently with IPCLI’s founders, George Rogu, M.D., and Juan Espinoza, M.D.

Topics covered include:
- What is a CIN
- Obstacles to forming a CIN
- What steps are needed to form a CIN
- Learning from other practices
- The impact on value-based care
- And more

Check out the interview at MedicalEconomics.com

“When you layer that support on a value-based incentive program to improve care and lower costs, then you’ve built a structure where independent physicians can thrive and everyone wins,” Crow says. “Our business model is to keep people healthy. That means the physician is being rewarded for providing better care rather than just seeing more patients. The patient wins by being kept healthier, and payers win because costs are lower.”

Providing a lifeline

The network has proven especially useful during the COVID-19 pandemic, Crow says, by helping practices pivot to telehealth, obtain supplies of personal protective equipment, and set up drive-through clinics — actions that few would have been able to accomplish individually. “We were a lifeline for a lot of them,” he says.

Blue Cross and Blue Shield of Texas (BCBSTX), one of the region’s major payers, supports Catalyst’s model of bringing independent practices together to improve value, says Rick Haddock, vice president of network management at BCBSTX. “We saw the value of trying to aggregate independent physicians to manage total cost of care while improving the quality of care by providing data in a non-risk-based environment,” he says.

Today Catalyst includes about 1,000 primary care doctors, Crow says, adding that rather than having to recruit members, practices now are asking to join. “When we started this, the attitude of some docs was, ‘I don’t want to deal with data, and I don’t need anyone to help with my patients.’ But many of them have come around and now say, ‘This is exactly what I need.’”

Pediatrician George Rogu, M.D., has a story similar to Crow’s but on a smaller scale. The owner of three pediatric practices and a pediatric urgent care center on Long Island, New York, Rogu had watched with dismay as nearby pediatric practices joined hospital
systems or closed their doors because they could no longer compete financially.

In response, Rogu began organizing informal meetings with fellow pediatricians to brainstorm ways they could cooperate to strengthen their individual viability without breaking antitrust laws. “We all had the same goals: to practice good medicine and take care of our patients,” he recalls. “But everyone was afraid to even speak to anyone else because we thought it might look like collusion. Also, it meant overcoming the habit of seeing each other as competitors.”

From informal discussions to clinical integration

At first, Rogu’s meetings focused on sharing best practices for dealing with common practice management challenges. But they soon evolved into discussing ways the participants could work together more formally. The result: In 2018 the Independent Pediatric Collaborative of Long Island (IPCLI) was created; the CIN is headed by Rogu and today includes about 50 providers in 10 practices.

A key to the collaborative’s operation, Rogu says, has been the ability to monitor the quality of care provided by its doctors. It does so through use of a “clinical dashboard” — a software program that synthesizes quality data taken from participants’ electronic health record systems and, with some massaging from information technology staff, organizes and presents the data as though they were coming from a single organization.

“The dashboard lets us quickly see how the organization is doing as a whole and breaks the data down by practice and even by individual doctor on a particular measure,” he says. He cites the example of a doctor in the network who was having trouble meeting measles, mumps and rubella vaccination metrics for her patients. “We were able to suggest a few simple tweaks that brought her numbers to where they needed to be,” he says. “Our thing is to provide good clinical care and share resources for the benefit of our patients.”

Using that quality data has enabled the collaborative to sign a value-based contract with a Medicaid program, and it is negotiating similar contracts with two other payers, Rogu adds.

IPCLI has also helped its participating practices lower overhead costs by creating greater bargaining power with vendors. For example, prior to forming the collaborative, each had used the same vendor for medical waste disposal. But the greater size of IPCLI enabled it to contract with a different company and pay substantially less. Disposal costs for Rogu’s practice dropped from $1,500 per month to $150.

“With IPCLI negotiating and managing the contract, everyone benefits,” he says. The collaborative’s group purchasing power has also reduced participating practices’ costs for vaccines, malpractice insurance and some employee benefits.

Asked what advice he’d offer to others thinking of forming a CIN, Rogu says, “It takes a lot of time because docs aren’t used to working together. The mentality used to be, ‘Whoever has the most patients wins.’ Now it’s, ‘If you win, I win.’”

— George Rogu, M.D., president, IPCLI

“It takes a lot of time because docs aren’t used to working together. The mentality used to be, ‘Whoever has the most patients wins.’ Now it’s, ‘If you win, I win.’”

— George Rogu, M.D., president, IPCLI
Malpractice liability is one of those issues that keeps many physicians awake at night, particularly this past year. Dealing with the effects of the COVID-19 pandemic — and the resulting increase in the virtual and remote care they’re conducting — made it an especially challenging time. Making matters worse, COVID-19 cases are spiking across the country in the middle of flu season.

So how can physicians ensure they’re doing everything possible to minimize their liability? Medical Economics® sat down with David Feldman, M.D., chief medical officer of The Doctors Company Group, the nation’s largest physician-owned medical malpractice insurer, to discuss strategies for physicians to protect themselves from liability while treating patients during this unprecedented crisis.

The transcript was edited for length and clarity.

Medical Economics® (ME): What are some of the liability issues surrounding this pandemic? Are we actually seeing malpractice cases resulting from COVID-19 yet? Or is it still too early in the process for that?

Feldman: We are too early. There have been a handful, a very small number. But we know malpractice is always lagging behind other things. We know that if you’re looking for malpractice as a leading indicator, you’re looking at the wrong thing. It takes years for these things to happen. So right now it’s a little too early to tell.

ME: What are some of the liability risks from COVID-19? What should physicians watch out for?

Feldman: The real answer is misdiagnosis. That’s the one thing we want to be careful about right now. Adding to that, clinicians are stressed, patients are anxious and testing is difficult. All of that just makes it even harder for clinicians to be sure they’re making the right diagnosis.

People are afraid to go to a doctor’s office. So we’re doing virtual visits, which I believe is a great thing. But they’ve got their issues. There have been very few malpractice cases around virtual visits in the past because (physicians didn’t do that many of them). But for the cases we’ve had, a lot of them have been around misdiagnosis.

So misdiagnosis is the one thing we really want to be careful of during this time. One of the resources we have on our end is on our website. If you read our recent article about the flu versus coronavirus, you’ll see this talk about the concept of system thinking. And this is certainly not my idea. It’s way above my cognitive abilities. But the idea is that, as human beings, we think with two different systems. There’s one system that’s sort of our automatic thinking — which I used to commute to Brooklyn every day from New Jersey when I was working at a hospital there. And if you had asked me when I got home how my drive was, I’m not sure I could have even told you, right? Because I was working on system one.

System two is the more cognitive way that our brains work. And if you think about when seeing

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Why Value-Based Care is a Better Way to Practice Medicine

By Patricia Hayes, M.D., an internal medicine physician and Texas Area Medical Director for Partners in Primary Care

Most physicians have long been frustrated by the number of patients they have to see in a day and the time pressures of those visits. On top of that are the hours devoted to administrative tasks that eat up the time they would rather spend caring for patients. According to studies of time demands on physicians, primary care doctors would need 18 hours a day to fulfill all their responsibilities. It's a prescription for burn-out.

Much of the problem rests with the traditional fee-for-service (FFS) payment system that forces physicians to do most of their work single-handedly, while pushing the size of patient panels upward. Shuttling patients in and out of exam rooms in 15-minute increments does not make for good care or job satisfaction. In that short time frame, it’s rarely possible to build strong relationships with patients and have in-depth conversations that could reveal the factors at the root of their health problems.

Having spent my medical career practicing in underserved communities, I know that addressing those underlying issues and social determinants of health—such as food and housing insecurity, and emotional health—is essential to improving a patient’s overall health. Under an FFS model, there is neither the time nor the resources to provide that care, which is why I’ve become a proponent of the value-based care model.

The Difference A Care Team Can Make

I am a practicing physician in Houston and the Texas area medical director for Partners in Primary Care, a company committed to a value-based, care-team practice model throughout its network of senior-focused medical centers. The team approach is critical to providing comprehensive care to our older patients, many of whom have chronic and complex conditions, as well as psychosocial risk factors.

Because others on the team handle much of the paperwork and assist with the non-medical care of patients, our physicians can focus on what we trained and love to do—care for patients. By limiting our patient panels, we have extended time for patient visits—45 minutes on average—allowing us to establish a true rapport and understand their health goals and needs, and the support systems they have in place or may require. Having a behavioral health specialist and social worker as part of the team also enables us to provide patients with needed mental health and social services.

During the pandemic, the care team has become even more essential for providing care beyond the walls of our medical center, keeping in frequent contact with patients through tele-health and even curbside visits.

Value-Based Care Done Right

To make the value-based care model succeed, the leadership charged with implementing it must fully commit to doing it right. Far too often, the focus becomes about performance metrics, which doesn’t work without the necessary resources in place.

Besides properly staffing and resourcing a care team, other essential ingredients for a successful value-based care team practice include:

- Defining each team member’s specific function
- Delineating the triggers that require specific members of the team to engage with a patient
- Scheduling regular meetings with the entire care team to discuss individual patient cases
- Establishing a collaborative work environment and emboldening every member of the team to share their recommendations
- Communicating that quality, not quantity, of care determines bonuses for every member of the care team, from receptionist to physician

A true value-based care system will require physicians to be better educated about the model, which should start as early as medical school. Doing so will help ensure that value-based care is implemented as it’s meant to be so that patients and physicians reap its benefits.

Dr. Patricia Hayes is the Texas Area Medical Director for Partners in Primary Care and is a practicing physician in Houston. She earned her medical degree from the University of Texas Health Science Center, Houston and completed her residency in Internal Medicine and Pediatrics at Baylor College of Medicine. Dr. Hayes chose to pursue her passion for medicine as a way to positively impact the lives of others in her community.

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**Continued from Page 11**

patients, you want to be careful not to use system one too often, right? Patients come in with something, and you go right to what you think it is. And then you think, “Well, wait a second. Let me take a step back and think because it may actually be something else.”

And that’s a really interesting way of thinking about how we treat patients during this time, with all these other things happening at the same time that can really impede our ability.

**ME:** What practical steps should physicians do to protect themselves from liability?

**Feldman:** I oversimplify things by using what I call the three Ps. The first P is preventing adverse events. Patients have diseases. Doctors treat them. Can you make sure that things don’t go wrong? We can’t always do that. We know that in the overall world of patient safety, probably half the things that go wrong can be prevented, and we keep getting better at it. Certain things that we put in place allow us to prevent bad things from happening. But we know we can’t prevent all adverse events.

The second P is: Can we preclude a malpractice case even in the face of an adverse event? The good news about malpractice, if there is such a thing, is that it’s pretty rare. Even when there are adverse events, it’s not typical to have a lawsuit. And most of us believe the way we can avoid a lawsuit, even in the face of an adverse event, is with communication — how we communicate with patients both before and after an adverse event happens.

I used to have a mentor who once said: “When you talk to patients about complications before a procedure, that’s informed consent. When you talk to them about complications afterward, it’s called an excuse.” So there needs to be this continuum of doctors talking to patients and families at the beginning of treatment, during treatment and after treatment. And that’s just a great way to avoid malpractice, even when things go wrong.

And the final P is about prevailing in a lawsuit, and that is about documentation.

So think about the three Ps — prevent adverse events, preclude by improving communication and prevail by improving documentation — in the context of the coronavirus pandemic. How do we protect our patients from adverse events? We’re talking about having the right (personal protective equipment), taking the usual precautions so there isn’t an adverse event and treating them properly. That’s the most important thing. But also we talk about communication and informing patients of risks, right? Talking to them about the things that we hear about all the time: wearing masks, washing your hands, watching your distance with other people. Those are the things that are going to keep people safe before vaccination.

Now we’re starting to talk about vaccinations. It’s very exciting. And I certainly tell the patient to get a flu vaccine. That’s important too. … And then talk to patients and families about prevention of other illnesses and make sure they’re getting their routine screening, which is really a concern to a lot of people.

ME: In regard to those important screening tests, how should a physician protect themselves if a patient has not been screened? How should that be handled if this sort of gap in potential care occurs?

**Feldman:** It’s just writing down in your chart what the communication has been with your patients to let them know they really need to come in and get their preventive testing done. That you’ve called patients to follow up with them, that your office staff has been in touch with them. It’s really documenting everything. You want to be able to look in the chart and see that you did all the right things.

**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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– Glenn Soppe, MD
Private primary care practice in Encinitas, CA

The right membership model stabilizes your practice with a new revenue source, and improves your patient relationships.
8 budget-friendly ways to market your practice during COVID-19

by Lisa A. Eramo, MA Contributing Author

Today’s physicians have a lot on their plates, and marketing the practice may not be at the top of their priority list. However, experts say this is the ideal time to connect with new and existing patients, serve as a resource and explain how to access care.

Why is marketing the practice important, particularly during the COVID-19 pandemic? It’s absolutely essential for patient retention, says Stewart Gandolf, MBA, CEO of Healthcare Success, a full-service health care marketing and advertising agency in Irvine, California. “Doctors by and large overestimate the loyalty of their patients,” says Gandolf. “Competition is accelerating with leaps and bounds.”

Independent practices compete with hospital-owned practices, urgent care centers, virtual care providers and pharmacy-based walk-in clinics—all of which have large marketing budgets, notes Gandolf. During COVID-19, patients may be more willing to switch providers if they perceive that those other entities provide safer, more efficient care, he adds.

Marketing also can also help physicians attract new patients, says David Zetter, CHBC, founder and president of Zetter HealthCare, LLC, a full-service practice management consulting firm in Mechanicsburg, Pennsylvania. However, before investing in marketing efforts, physicians need to ask this important question: Are there enough providers and medical assistants to handle an increase in patient volume? “I wouldn’t be marketing if you don’t have your act together,” he adds.

To attract and retain patients, consider the following eight budget-friendly ways to market your practice.

Invest in search advertising
Search advertising (e.g., a Google ad) is a text-based ad that appears at the top of search engine results when a user searches for relevant terms (i.e., internist near me). The service uses a pay-per-click model, and physicians can expect to pay approximately $3 per click for a Google ad, says Rachael Sauceman, head of strategic initiatives and internet marketing at Full Media, a health care digital marketing company. Cost per click is determined largely by the keywords used in the ad, she explains. The more competitive the keywords, the more expensive the ad.

“In our experience, searching advertising is the best lead-generation tool,” says Sauceman. “We don’t recommend other types of advertising unless they have done this first.”

Unlike expensive newspaper, radio or TV ads, Google ads are cost effective and agile, enabling physicians to easily update their message, says Sauceman. For example, did the practice adjust its hours to accommodate patients who are symptomatic for COVID-19? Has the practice taken additional precautions to keep patients safe? Physicians can update a
Google ad in seconds to include this new information.

Search advertising is also all about timing. “If you get in front of patients on social media or the newspaper, you might get in front of a lot of people, but they’re not looking for a provider necessarily right at that time,” Sauceman says.

“With Google, they are. If you get in front of them at that critical decision-making time, then you have the ability to influence that decision.”

**Update the practice website**
Overexplain the in-office and virtual care experiences, says Sauceman. “It’s easy to forget the amount of confusion that’s out there and the fact that every practice is doing things a little differently.” She suggests including a step-by-step explanation of what patients can expect upon arrival to the practice or when they check in for a telehealth appointment.

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**Grow your practice with email marketing**

By Hoala Greevy Contributing Author

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The following guidelines will help you develop an effective email marketing plan for your medical practice.

**Stay on the right side of HIPAA**
First and foremost, be sure to comply with HIPAA rules surrounding marketing to patients. To that end, we have written a detailed explanation of how HIPAA defines marketing and what this means for you.

In a nutshell, covered entities are allowed to market to patients, but in some cases, prior authorization is required, either written or electronic.

In regards to email marketing, most mainstream email marketing platforms will not sign a business associate agreement (BAA), and most of those that do will not allow you to transmit PHI. Make sure you only partner with an email marketing solution which is fully HIPAA compliant.

**Build your email list**
There are various ways to encourage patients or potential patients to opt-in to receive marketing emails from you. For example, you can include a marketing authorization form in a new patient’s intake paperwork or provide a signup link on your website.

**Tell people what’s in it for them**
When people are opting in, mention what your emails will include, whether that’s free guides about preventative care, or simply a monthly healthcare email newsletter.

Making your emails’ value clear increases the likelihood of patients checking the opt-in box.

**Segment your email lists**
Every email campaign won’t apply to every patient, so tailor messages to the correct audience.

For example, if you’re sending an email to senior citizens, mention how the new pneumonia vaccine could keep them healthy. If you’re sending emails to parents, consider sending information about how they can prevent their children from catching the flu.

Personalization demonstrates that you care about your clients’ well-being, which makes them more comfortable trusting your practice with their healthcare needs.

**Provide a clear, useful message**
Make sure that your message is explicit. Clearly explain the intention of your email, such as confirming an appointment or information about what healthcare services your business offers.

Successful email marketing engages readers with content that benefits them. Patients will be more likely to open and read a message that solves their problem or is genuinely useful or interesting.

**Get to the point**
Your patients are busy people, so they don’t have time to read an email manifesto. Keep your emails short and sweet.

Short messages are also better for mobile. This is hugely important, considering 55% of email is opened on mobile devices.”
appointment, how they’ll interact with physicians and staff, and what happens after the appointment. Consider devoting a section of the website to COVID-19-related education, Zetter advises. “There’s a lot of bogus information out there,” he says. “What can you do to unmuddy the waters? What are you going to do so your patients see you as the expert on their care and well-being? You want people to trust you and rely on you for information.”

Another idea is to provide a section devoted to financial resources, says Sauceman. Examples include links to patient assistance programs, a transparent list of costs for common services or contact information for the practice’s billing staff so they can answer questions and clarify invoices.

“Many patients are experiencing financial hardship or a loss of insurance at this time, so if price or the types of insurance you accept are a competitive advantage for you, it’s a good time to make that transparent,” she adds.

If possible, try to obtain backlinks from other reputable sites because this helps with search engine optimization, says Gandolf. For example, if a physician typically donates to a local Little League team, is the team willing to include a link to the practice’s website on its own site?

Most importantly, explain why the office is a safe place during the COVID-19 pandemic. For example, post pictures of staff wearing personal protective equipment, of hand sanitizer stations or of the Plexiglas-protected front desk. Also include a bullet point list of what the practice does to ensure a clean environment (e.g., we thoroughly clean exam rooms after each patient or our medical assistants put a sign on each waiting room chair immediately after someone is called for their appointment so front desk staff know to clean the chair before another patient sits in it).

Physicians can also create a free YouTube video that details what the practice is doing to keep patients safe and then embed that video on their website, Gandolf says. “It doesn’t need to be fantastic production quality. It’s about reassuring patients that it’s safe to come in.”

**Use HIPAA-compliant texting**

Secure texting complies with federal law restricting release of medical information, enabling practices to text preventive health reminders (e.g., call to schedule your physical or don’t forget to come in for your flu shot), appointment reminders, marketing of new services and other health tips, says Zetter. “There are all kinds of things you can do to keep your name in the forefront of patients’ minds.”

**Offer in-demand services**

For example, flu shots and COVID-19 tests aren’t big revenue generators, but they’re ways to introduce physicians to new patients, Gandolf notes. Telemedicine is another example. Patients want this service, and practices that don’t offer it will be largely overlooked, he says.

**Leverage social media**

Travis Withers, operations manager at Essence of Health Wellness Clinic, a direct primary care medical practice in Chattanooga, Tennessee, posts two or three updates per week on the practice’s Facebook and Instagram pages, mostly providing helpful health tips and other timely health-related information.

“We have created posts about the importance of handwashing, benefits of a plant-based diet and the importance of flu shots, among many other topics,” he says. “In addition, every Friday we do a 10- to 15-minute Facebook Live on a health topic, (and) we take questions. Several new patients have told us that they followed us on social media for months before joining the practice.”

**Sign up for a Google Analytics account**

This free service integrates with most websites and provides physicians with insight into total views, page views and more, says Sauceman. It can also track contact forms or appointment requests made through the practice’s website back to a specific ad or other source. This helps physicians understand whether their marketing efforts are paying off. For example, if they placed a paid ad on social media, they could monitor whether that ad has successfully led patients to schedule an appointment.

Linking Google Analytics to a practice website is easy. Most websites simply require users to input their unique Google Analytics identifier code — a number that can be obtained under the administrative settings of the Google account. The rest happens automatically behind the scenes.

**Update your Google My Business listing**

Google My Business is a free tool that enables physicians to promote their business profile and website on Google search and maps. Physicians must verify their business before they can make changes to their listing.

“An up-to-date and thorough listing not only pleases prospective patients, it also pleases Google,” Gandolf says. “Google rewards businesses that take the time to create robust profiles and respond to reviews by increasing their visibility in search results.”
A
ccording to a recent report from the *New England Journal of Medicine*, female primary care physicians generate 10.9% less revenue from office visits compared to male physicians, despite spending 2.6% more time in the office with patients. Although female physicians had a lower volume of patient visits, they spent almost 16% more time with each patient. During this additional time, researchers found that female physicians placed more medical orders and discussed more medical diagnoses and preventive care than male physicians.

This begs the question: Why are women not being paid for their additional labor? According to the study, the answer seems to be that male physicians are simply better at billing for their work than female physicians, including billing based on time. Also, female physicians in procedural fields like radiation oncology were less likely to bill for “lucrative procedures” than male physicians.

Here’s the good news: This is one type of gender pay difference that is easy to fix. Female physicians can either opt out of a broken health care system that rewards short visits and high billing codes and enter into a direct primary care (DPC) model, or they can invest some time learning how to work the system to their advantage. As a female family physician, I’ve done it both ways. Although I advocate for the former (DPC has been a life changer for me), I was also able to out-earn many of my male colleagues in traditional practice by learning how to outsmart the system.

What follows are my top tips on how female physicians can close the gender pay gap in a practice using the relative value unit model.

By **Rebekah Bernard, M.D.** Contributing Author
Don’t give away your time
Unlike attorneys, a physician’s billing clock only starts ticking when we have a face-to-face encounter or formal telemedicine session with a patient. Phone calls and emails reviewing lab results are not compensated. Medication refills, prior authorizations, insurance forms, disabled parking passes, jury duty excuses, school medical excuses — physicians are not paid for any of these services, even though they may take a considerable amount of time (family physicians spend nine hours per week on uncompensated labor).

The reality is that in a fee-for-service insurance model, the only way to be fairly compensated for work as a physician is to see patients in the office. So rather than calling or emailing lab results, schedule your patient to return for a visit to review results together. If a patient calls with questions, concerns or clarifications, ask them to schedule an office visit. After all, an office visit is almost always the best way of evaluating your patient and providing the best medical care.

In addition, every time a form appears on your desk to be filled out, forward it to your office scheduler with a note to bring the patient in for an office visit. Doing paperwork while the patient is in the office not only allows you to bill for your work, it also saves you time: The chart is ready for you, the patient can directly answer many of the questions on the form and you have the opportunity to address medical concerns that relate to the paperwork, such as changing a medication or requesting prior authorization for a medication that is medically necessary but not covered by the patient’s insurance.

Be available for your own patients
Don’t miss out on quick, easy visits like urinary tract infections or minor skin infections because you lack schedule availability. With the current system of coding, a minor issue that you can attend to in five minutes is reimbursed just a bit less than a visit that takes you 30 minutes and loads of cognitive effort. The best way to ensure availability is to block several slots per day for urgent, acute care visits. These can be dispersed throughout the day or reserved during certain intervals, such as the last hour of the morning or the end of the day.

Schedule frequent follow-up visits
It is simply impossible to attend to every single problem that a patient has in one visit, along with addressing preventive care, although it’s clear from the New England Journal of Medicine study that female physicians certainly try their best! We need to accept that we can’t do it all, and instead, prioritize the most important issues and ask our patients to schedule follow-up visits. This can be difficult, as many of us are “people pleasers” and fear letting down our patients. We also worry about patients’ schedules and causing an additional copay. However, we need to accept that one of the keys to quality health care is developing a long-term relationship with a patient. Having the same physician over time reduces patient mortality by allowing more opportunities for us to explore our patients’ health and intervene in their lives. Remember: You cannot address a lifetime’s worth of problems in a single 15-minute visit, and you must not expect this of yourself.

It’s especially important to schedule frequent follow-ups with
patients who have serious chronic health conditions or underlying psychological conditions like anxiety disorder. Some of these patients are prone to showing up without appointments, often in crisis, and can severely impact the day’s schedule. By scheduling frequent follow-up visits, you eliminate some same-day, “urgent” appointments. Frequent visits are reassuring to patients, many of whom fear abandonment. It also helps to tell your patient how much time you have scheduled for them at their appointment, to help them prioritize what is most important.

**Capture add-on codes**

When families come into the office together, “surprise” visits can cause a strain. You know the situation. You’re in the exam room seeing a well child when Mom points to a sibling and says: “Can you just check his brother’s throat? He’s been complaining that it hurts.” Or you’re seeing a husband and wife together, but just one is scheduled for an appointment. Inevitably, the conversation turns to a concern about the other spouse’s health.

This creates a dilemma. Although you could ask the “add on” patient to schedule an appointment to discuss their issues, it may be quicker and easier to address the problem directly. However, don’t forget to capture a billing code for your work. Even if you spend minimal time, you are likely to garner enough information to capture at least a level 99212 code for the work you did.

Also don’t forget to ensure that you properly bill for wellness visits and screening codes. The most efficient way to do this is to create a template or form. I also recommend including the dates of your last preventive screening in your problem list, where you can see at a glance what services are due.

**Don’t sell yourself short**

Female physicians must take the time to learn how to code accurately to be fairly paid for their work. Often, we underestimate the amount of work we’re doing and undercode. Yes, it seems unnecessarily complicated, but a few steps can make it easier. First, remember that billing codes are driven by the extent of medical decision-making. If a patient has a new problem, requires additional evaluation like blood tests or needs a prescription medication, they are likely going to warrant a higher level of service. If a patient has a life-threatening condition, you need to call 911 or you are going to really worry about the medication you must prescribe, then the level of service increases to the maximum. To ensure that you are checking all the right bullets, consider posting a chart of coding requirements for history, physical and medical decision-making next to your computer.

As a physician, you should never be coding a 99211, which is a nursing code for an evaluation ordered by a physician, like a blood pressure check. If you take a quick look at a patient and make a straightforward recommendation, you have earned at least a 99212.

Don’t forget to use time-based documentation when you spend the bulk of your visit “counseling or coordinating care.” For example, time-based coding will likely come into play with the patient who comes in severely depressed or has a stack of forms for you to fill out. While you don’t have to do lots of documentation for history or physical, you do have to document the time spent, both total and counseling time, and the details on the counseling/coordination of care activity.

**Don’t be afraid of procedures**

Our current system rewards interventions more highly than cognitive services. Primary care physicians should take advantage of this to serve patients. The key to success is having proficiency in your procedural skills and developing an established protocol for each procedure that you perform in the office.

If you didn’t have the opportunity to practice many procedures in your residency, many courses are offered at continuing medical education conferences. Another way to gain expertise is to find a physician mentor who does procedures in the office. Of course, be sure to know your limitations, and when in doubt, refer the patient to the appropriate specialist.

Before performing a procedure, break it down into individual steps. Create an organized list of supplies and actions required. Be sure that you have all the proper equipment ahead of time, and get the best equipment that you can afford. Develop a plan for follow-up and a patient handout, if necessary, for after the procedure. Using your prepared protocol, your medical assistant should be able to quickly ready the exam room for the procedure. Also make sure that your patients know that you offer office procedures so they can contact you if they need help, rather than visiting an urgent care or specialist.

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There’s nothing like landmark regulation released during a time of great uncertainty.

On May 1, 2020, the clock began ticking for health plans, providers and information technology (IT) developers to implement the Centers for Medicare & Medicaid Services (CMS) Interoperability and Patient Access final rule. For all of us struggling to cope with the COVID-19 “new normal,” there is more at stake with this coming wave of interoperability than may meet the eye. Now is the time to plan and take action.

Put simply, individuals will have the option to take greater ownership and accountability for a broader and consolidated set of electronic health information (EHI) and, with individual consent, share that information with their health plan and providers. This will be supported by the creation of a system of regionalized data brokers who arbitrate the exchange of electronic health information with and from CMS-regulated health plans, providers and IT developers according to defined patient consent parameters. This new approach — the Trusted Exchange Framework and Common Agreement (TEFCA) — is still
LEGAL / NEW INTEROPERABILITY RULE

being considered by regulators but will likely follow the National Information Exchange Model (NIEM), a proven federal approach for the exchange of data within and across industries, including the Department of Homeland Security. This likely means that in the future:

- Data brokers (Qualified Health Information Networks [QHINs]) will arbitrate the parameters for all patient EHI transfer, including B2B from developers to health plans/providers.
- Federally certified IT developers will have access to the same core data set as health plans and providers and be focused on creating value for patients through the development of new digital products that will enable more transparency, efficiency and choice.
- Individuals will move through the health care ecosystem with their EHI based on tiered levels of consent, with a core data set that is opt out for exchange, but with higher tiers of confidential EHI that patients must opt in for sharing.

“At its core, this rule is about transparency and giving individuals the ability to move across health plans and providers and have ... information move with them.”

Make no mistake, the new rule will create disruption in the health care marketplace. Federal regulators are doubling down on the idea that creating a more open system of exchange to a publicly owned virtual clearinghouse of claims and clinical data will force competition and innovation that is good for health care consumers. When the wave breaks, the health care landscape will look very different from today.

Why is interoperability particularly important to providers?

Historically, health plans and providers have been understandably reluctant to share information both for competitive and regulatory reasons. However, as the new rule is implemented, consumers will exercise increasing control as to how and with whom their EHI is shared. This will usher in unprecedented risk, including risk to privacy, as third-party developers are able to directly access patient data, and risk to monetization of data with the rise of new applications that circumvent traditional regulatory gatekeeping policy. Understandably, the costs to establish, maintain, audit and retain EHI will be borne by health plans, providers and potentially patients.

To stay relevant, health plans will need to embrace this new reality via a consumer-focused strategy and not just check the box. Survival requires not only getting on board with these newly defined needs but getting in front of them by putting the member at the center of value creation, while transforming how data is tracked and managed. This may take some deep, authentic introspection, and asking questions such as:

- How do we seamlessly identify and capture member consent for data exchange so that we can remain viable for members and have the information to support high quality care?
- Where do members and their families most often get stuck trying to navigate care and advocate for themselves — both within and outside our clinical network — and how can we help?
- How do we safely and securely support the right level of transparency for members to get the right care at the right time?
- What customer-experience tools and incentives can we provide members and group plans to help us prioritize and better target our population health programs?
- How can we use the new rule to build a relationship with providers that puts the patient at the center and moves us away from being at odds?
What does this rule mean for patients?

At its core, this rule is about transparency and giving individuals the ability to move across health plans and providers and have both their clinical and administrative information move with them and be accessible throughout their journey. Bottom line, certified IT developers will empower individuals to actively engage in their health care in an unprecedented way, through a seemingly limitless set of new use cases, such as these, at the highest level:

- Before patients decide where to buy insurance coverage, they can see if their doctor is in a health plan’s clinical network, and they will have a better way of comparing health plans offered by a variety of payers.
- Through a single application, patients can access current and historical health insurance data, and clinical data from all visits, regardless of a doctor’s EHR. The patient can see things such as scheduled appointments, lab results, diagnoses, referrals, prescriptions, authorizations, deductibles and copays.
- When a patient arrives for a new specialist appointment, they do not need to fill out the same paperwork yet again. Five-plus years of cumulative EHI can be instantly transmitted through an authentication process between their phone and the specialist’s EHR.
- Patients, providers and health plans will have better information to navigate the health care system and reduce the risks to the patient that come from incomplete information.

Key drivers for providers

**Customer experience**

Ensure your brand strategy is centered on trust and establishes an authentic emotional connection with your members. Every member acquisition and retention touchpoint should be crafted with care, not only providing the information required but finding ways to anticipate member and prospective member needs. Also be sure your digital products and services are effortless to use, removing all points of friction and finding opportunities to increase engagement by personalizing content via insight from customer data. A well-designed customer experience will build brand preference, increase conversion and result in long-lasting relationships.

**Strategic partnerships and vendor management**

Understand your health information exchange and ensure you’re informed, proactive and strategic in how to collaborate with QHINs. Don’t just turn on FHIR APIs as a check-the-box exercise. Develop short-, medium- and long-term strategies to identify, vet and partner with ONC-certified third-party developers to capitalize on innovative ways to improve patient experience and support better care coordination, both during a pandemic and in the new normal. Establish partnerships with QHINs and certified developers that enable a shift from seeking to control customer data, to a stewardship model that empowers member access. Prioritize your digital product development and vendor selection roadmap to remain relevant and viable as a business.

**Regulatory compliance and data security**

Have proven-effective compliance policies to inform third-party developer vendor selection. Ensure you have the right people, processes and technology for effective delegated entity oversight of interoperability technology vendors. Include new governance models for member consent, data sharing, patient privacy and data security, and monitor and audit systems and

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WHAT TO EXPECT

In the near term, the industry will continue to lobby for scaled-back regulatory requirements and a longer implementation timeline. There will be operational pressure for health plans and providers to comply by adopting new technologies, workflows and governance models, as well as new investment and rapid growth of third-party developer solutions combined with a race to prototype, test and market these products.

Longer term we will see:

- Incremental improvements in patient access to EHI and provider directory data leading to a higher level of discernment in customer product choice.
- Higher precision in matching patients to clinical history, medical needs, social determinants of health and physical/digital location; significant data security risks and more reliance on strategic partnerships and trusted health information networks/exchanges for reliable sharing of EHI.
- Increased market competition stemming from a need for digital products and strategies to attract and retain patients and networks.
- Improved care coordination, continuity and quality of care resulting from a portable, digital patient health record, better data standardization and improved B2B interoperability.
- Accelerated adoption of value-based payment models resulting from a growing cumulative patient record and corresponding ability to more accurately measure patient outcomes and risk stratify needs (medical, behavioral and social determinants).
- Voluntary commercial insurance adoption of standards and rules.
- Further industry consolidation.

How should you respond?

First, it’s important to understand where you’re at and where you need to go. This includes launching a readiness assessment, governance, program planning and execution. Whether you’re a family practice in a retirement community or a publicly traded insurance carrier with a Medicare Advantage plan, you’ll need to evaluate options, ensure you meet the requirements, and align resources to pivot to take advantage of the changes coming.

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Operational Integration as a Competitive Advantage

Have best-in-class operational and technological capabilities to support members in their care journey and operational and technological capabilities to support providers in care coordination. Build in the ability to adapt quickly to evolving federal trusted exchange requirements, and ensure your member enrollment processes capture data-sharing consent. Include rapid risk stratification and predictive modeling at member enrollment, and take a proactive approach to member outreach, coordination and care management. Improve quality measurement to direct value-based care/payment and cost-containment investments.

Understanding the trusted exchange and how to work with it can provide you with a key strategic advantage. To stay relevant in the new normal, understand the evolving trusted exchange and interoperability rules and develop the infrastructure to integrate them into your business, invest in partnerships that enables best-in-class-data as service to drive customer experience and optimize your relationship with trusted exchanges.

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The COVID-19 pandemic is an unprecedented public health crisis that has disrupted millions of lives globally. This “new normal,” in which people’s homes have become their office, gym, school and more, has impacted everyone differently. Some, perhaps, were already telecommuting to work or home schooling their children; however, for others, this transition has been difficult.

Take patients with migraines, for example. When asked how the COVID-19 pandemic has impacted her migraine patients, says Susan Hutchinson, M.D., a headache specialist, family physician and founder of the Orange County Migraine & Headache Center in Irvine, California, “For about one-third of my migraine patients, their migraines are better, one-third are worse and one-third are about the same.”

Increased stress may be part of the problem
To further understand just how much the pandemic is affecting adults in the United States, the American Psychological Association (APA) adapted its annual Stress in America poll into a monthly analysis of stressors and stress levels. The online survey was conducted from April 24-May 4, 2020, by the Harris Poll on behalf of the APA and included 3,013 U.S. adults ages 18 and older.

The findings showed that the average reported stress level for U.S. adults related to the COVID-19 pandemic was 5.9 on a scale of 1-10 (1 meaning “little or no stress” and 10 meaning “a great deal of stress”). Regarding stress level in general, the average reported stress level was 5.4, which marks the first significant increase in average reported stress among U.S. adults since the survey started in 2007, according to the APA.

These rising stress levels are particularly concerning for patients with migraines, for whom stress is a common trigger. According to the American Headache Society, 4 out of 5 patients with migraines report stress as a trigger.

When asked how her migraine patients were managing during the pandemic, says Linda Davis, M.D., a family physician with Kolvita Family Medical Group in Mission Viejo, California, “I do think (COVID-19) had a negative impact and (that) they’re probably suffering from more (migraines) because of the stress.”

One source of stress for patients with migraines could be tension in the household related to home offices and remote learning. Such changes may have forced some adult patients with migraines to telecommute for work and/or home-school their children and younger migraine patients.

by Sydney Jennings Associate Editor

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Hepatic Encephalopathy: An Overview of Risk Factors, Management, and the Role of Primary Care Providers

**Pathogenesis and classification**

The pathogenesis of HE is not fully understood. In the presence of hepatic injury, urea synthesis in the liver is impaired, and astrocytes in the brain supplement the process. Within astrocytes, ammonia combines with glutamate, forming glutamine, an osmolite that increases cerebral volume and causes cytotoxic brain edema. Neuroinflammatory responses can also attribute to HE, especially when sepsis or infections are causative agents. Evidence increasingly suggests that the replacement of healthy gut commensals by potentially pathogenic substances and the activation of the γ-aminobutyric acid-benzodiazepine neurotransmitter system may also contribute to the pathogenesis of HE.

HE is determined by underlying disease, severity of manifestations, time course and the existence of precipitating factors. The prognosis of HE varies based on the underlying etiology. The disease is classified into three categories to guide management: disease due to acute liver failure (type A), disease due mainly from portosystemic shunting or...
bypass (type B) or disease due to cirrhosis (type C).\textsuperscript{1,2}

In covert HE, patients have subtle cognitive deficits and often appear to be asymptomatic.\textsuperscript{3} Psychomotor and/or electrophysiological testing often aids in the diagnosis of minimal HE. In overt HE, patients typically have signs and symptoms that can be clinically diagnosed without the use of psychomotor and/or electrophysiological testing.\textsuperscript{3} The severity of HE is most frequently graded using the West Haven criteria. The West Haven system differentiates four grades of HE, with grade one being least impaired and grade four being most impaired (comatose).\textsuperscript{1}

HE events can be episodic, recurrent (events occurring within ≤ six months) or persistent (pattern of behavioral alterations consistently present and interspersed with relapses of overt HE).\textsuperscript{1,8} The disease is subdivided into nonprecipitated or precipitated factors. Precipitating factors should be actively sought and treated when found.\textsuperscript{1} Common episodic and recurrent precipitating factors for overt HE include infections, gastrointestinal bleeding, diuretic overdose, electrolyte disorder, constipation and other undefined factors.\textsuperscript{1}

**RISK FACTORS AND BURDEN OF DISEASE**

HE is not only a common complication of liver disease but one of the most debilitating.\textsuperscript{1} It carries a significant burden on patients, caregivers and the health care system.\textsuperscript{8} As mentioned previously, patients who experience one HE event are predisposed to other events.\textsuperscript{29} In this scenario, a vicious cycle occurs: exposure to precipitating event, development of HE, manifestation of neurological/psychological abnormalities (hospitalization if severe enough), identification of precipitating event, avoidance of precipitating event, treatment of acute episodes and hospitalization discharge; the cycle then repeats itself with every event.\textsuperscript{1,8} As patients experience more and more attacks, poorer mortality rates ensue.\textsuperscript{11,12}

Patients with cirrhosis frequently experience HE within five years of receiving their diagnosis.\textsuperscript{9} Presence of certain risk factors (e.g., diabetes, hepatitis C and complications of hepatic encephalopathy, including infections, ascites, variceal bleeding) have been found to increase rates of occurrence of HE.\textsuperscript{1}

It has been reported that 21%-41% of patients with cirrhosis eventually developed overt HE and that history of overt HE significantly predicted the occurrence of future attacks.\textsuperscript{10} A random 20% sample of 166,192 U.S. Medicare enrollees with cirrhosis found that the overall incidence of HE was 11.6 per 100 patient years.\textsuperscript{13} In this analysis, 48,763 HE events were reported over 5 1/4 years.\textsuperscript{13} Significant risk factors included alcohol-related cirrhosis and portal hypertension.\textsuperscript{12} In a meta-analysis that evaluated the association of HE with survival in patients with liver failure, authors noted that HE was a negative prognostic factor for survival in patients with liver failure.\textsuperscript{16} Other data have also demonstrated that increases in frequency and severity of HE events correlated with poorer mortality rates.\textsuperscript{11,12}
Patients with HE also commonly experience decreased work productivity and problems with daily activities. These cognitive issues can impair the ability to drive and can cause motor vehicle accidents. Additionally, cognitive dysfunction may result in falls and other potential dangers. Socioeconomic status also can be affected when patients lose jobs due to suboptimal job performance.

In addition to the significant patient burden, HE is also associated with an increasing burden to the U.S. health care system. Using the 2010-2014 National Inpatient Sample, Hirode et al evaluated trends in clinical and economic burden of 142,860 hospitalized patients with HE. From 2010 to 2014, the total number of hospitalizations significantly increased by 24.4% (25,059 vs. 31,182, respectively; P < 0.001). During this time, inpatient charges increased by 46%, from $8.15 billion in 2010 to $11.9 billion in 2014. It is important to note that these repeated hospitalizations predispose patients to nosocomial infections that also negatively impact morbidity and mortality.

MANAGEMENT OF HE
The 2014 Practice Guideline on Hepatic Encephalopathy in Chronic Liver Disease from the European Association for the Study of the Liver and the American Association for the Study of Liver Diseases recommends a four-pronged approach for the management of patients with HE:
› Initiate care for patients with altered consciousness.
› Determine and treat alternative causes of altered mental status.
› Identify precipitating factors and correct them.
› Initiate empirical treatments for HE.

Pharmacological treatments for HE are primarily based on observational experiences versus rigorous randomized, controlled studies. Primary therapies include nonabsorbable disaccharides (e.g., lactulose) and antibiotics (e.g., rifampin, rifaxamin). Other therapies (e.g., oral branched-chain amino acids, intravenous L-ornithine, L-aspartate and probiotics) are also sometimes used.

ROLE OF PRIMARY CARE PROVIDERS
Although the diagnosis and management of HE has been traditionally done by a hepatologist, contributions from primary care providers and midlevel health care professionals (such as nurse practitioners) should not be ignored. Primary care providers are in an ideal position to assess patients at risk for developing HE. Common disturbances observed in outpatient settings that can be indicative of HE include sleep-wake issues, speech difficulties and disorientation. As HE progresses, personality changes (e.g., apathy, irritability, disinhibition), excessive daytime sleepiness and asterixis, or “flapping tremor,” can also occur. It is important to note that overt HE is commonly misdiagnosed with stroke.

Primary care providers can also play an important role in treatment. Up to 90% of HE cases can be treated...
by correcting the precipitating factor(s) and avoiding them in the future.¹ When patients are discharged from hospitals after acute events, follow-ups with primary care providers are needed so clinicians can monitor for precipitating factor(s) occurrence. Such interventions not only improve patient care but can prevent repeated hospitalizations.² Patient education (and caregivers, when necessary) about the importance of adhering to medications, monitoring for adverse reactions of medications commonly used to treat HE (i.e., lactulose, rifampin, rifaximin), evaluating for early signs of recurrence and acting quickly if recurrence occurs is an important service that primary care providers can provide.¹

HE CODING CONSIDERATIONS

International Classification of Diseases, 10th Revision coding system requires clinicians to document encounters in sufficient detail to be reimbursed appropriately.¹⁸ It is important for clinicians to be aware of challenges relating to coding of HE so appropriate reimbursement occurs.¹⁸

HE was reclassified as “hepatic failure.” Under hepatic failure, events can be classified as acute/subacute, chronic, alcoholic and/or drug induced. Importantly, all these codes as well as “unspecified” have the same impact on revenue and quality/performance measures. Clinicians may, however, assign great specificity to a diagnosis of hepatic failure based on notes in the medical record.¹⁹

When HE events are associated with “coma,” they must be documented in the current medical record using the “with coma” code. This is important, as it affects revenue and quality/performance measures.¹⁹ Patients only being described as obtunded or lethargic cannot be coded as “with coma.”²⁰

CONCLUSIONS

Primary care providers can play an integral role in the assessment, management and prevention of disease worsening of patients with HE. Adhering to medications of central components of patient and/or caregiver education that primary care providers play an essential role in delivering. Beyond education, understanding the disease course, common risk factors and overall burden of this disease is critical to ensuring timely and appropriate treatment. By evaluating for early signs of recurrence, and acting quickly if recurrence occurs, primary care providers may not only increase the likelihood of better treatment outcomes but also improve the quality of life for patients with HE.¹

REFERENCES

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switch from in-school learning to home schooling.

Millions of families are affected

Education Week, an independent news organization that provides comprehensive coverage on K-12 education, tracked pandemic-related U.S. school closures. From March 6-May 15, 2020, school closures impacted as many as 55.1 million students in 124,000 public and private schools nationwide at the pandemic’s peak.

In addition, a significant number of adults switched from working at the office to telecommuting if their job permitted. According to a Gallup poll conducted from March 30-April 2, 2020, 62% of employed Americans said they’ve been working from home during the pandemic (double the number working from home in mid-March). Although working from home offers some benefits, including increased flexibility and time spent with loved ones, for some, that extra family quality time may be a source of stress. “There’s a lot of tension in some households with kids home, Mom and Dad home,” Hutchinson says.

For example, a 12-year-old migraine patient of Hutchinson’s presented with headaches that had transformed into a refractory pattern. “After further discussion with the mother, she said the husband, because he’s stuck at home all day with the daughter, (is) angry,” explains Hutchinson. “He’s angry at the slow internet speed. He’s just angry at the world, and I think he makes his 12-year-old daughter feel like she’s somewhat responsible.”

The patient was also missing her friends from school, so Hutchinson told the patient’s mother, “I’m going to do what I can with medication, but all the medication in the world isn’t going to be able to get your daughter back to an infrequent episodic pattern.” Hutchinson advised that they look at the family dynamics at home to relieve some of the patient’s stress.

Davis shares a similar example of a patient who was doing well with her maintenance medications for some time, but she developed a migraine recently that would not break and came into the office for an injection. “We were talking about it, and she said that what’s been hard for her is normally when she gets in these cycles of migraines that she can’t break, there’s a reprieve at home. Home is ... her safe place (where) she can go lie down, she can relax,” says Davis. “But right now, she’s working from home, her husband’s working from home, the kids are being home-schooled. So suddenly, her stress environment is her home.”

Davis adds that the patient had to get in her car and take a drive to find some peace. “It was kind of an eye opener. ... I think maybe in the beginning, the migraines (were) a little bit less, but as time goes on, I think this (new normal) is becoming a trigger for (patients with migraines),” she says.

Pandemic impacts women and men differently

Female patients with migraines are a group of particular concern during the pandemic. Women have migraines three times as often as men, and migraine is also one of the leading serious health issues affecting women.

“I think the women probably are faring worse than men because women have children to take care of now who maybe had been going to school,” notes Hutchinson about her female migraine patients. “So all of a sudden, they have the school responsibilities. Many of them also have careers and jobs so they also have work responsibilities.”

A Kaiser Family Foundation Health Tracking Poll conducted March 25-30, 2020, included 1,226 U.S. adults age 18 and older and found a widening gap between men and women in self-reported negative mental health impact from COVID-19. Overall, 53% of women said worry or stress related to the COVID-19 pandemic has had a negative impact on their mental health vs 37% of men, and this gap widened more among parents of children under age 18 — with 57% of mothers vs 32% of fathers reporting their mental health has gotten
worse during the pandemic.

“There have been a lot of articles in the medical literature, sort of opinion articles, that (the pandemic) is going to set women back quite a bit in general because what’s going to happen is when the fall comes and their kids are not going back to school, somebody’s going to have to stay home. And usually it ends up being the woman,” says Davis. “It’s going to be a vicious cascade across the board because more of the home responsibilities are already still on the women.”

**COVID-19 impact on care for migraine patients**

Physician practices across the country have had to change the way they deliver care to ensure patient safety in response to the COVID-19 crisis.

An April 2020 survey of 8,421 U.S. physicians conducted by the physician search firm Merritt Hawkins, in collaboration with The Physicians Foundation, found that 48% of physicians are treating patients through telemedicine. This is a significant increase since 2018, when only 18% of physicians reported using telemedicine.

Peter McAllister, M.D., medical director at the New England Institute for Neurology and Headache and chief medical officer for the New England Institute for Clinical Research and Ki Clinical Research in Stanford, Connecticut, explains how being near the epicenter of COVID-19 cases drastically changed how he delivered care to his migraine patients. “The short answer is, it’s been profound,” he says. “Clearly with New York City being the epicenter of the number of cases and number of deaths — (and) we are just up the road in Connecticut. There were a lot of people being quite afraid to go out, understandably and quite reasonably.

“We had to make some big decisions at our practice. Some practices, neurological practices, closed their doors completely and have gone to a full telemedicine thing. My perspective was that we could probably thread the needle and do it safely to be at least partially opened.”

As now mandated by the Centers for Disease Control and Prevention for patient safety, McAllister and colleagues call all patients the day before an appointment to complete a questionnaire on potential COVID-19 exposure or infection; the questions are repeated upon arrival at the office, and temperature is checked. Patients and staff are required to wear a mask or other face covering.

McAllister and his staff also get tested for COVID-19 on a weekly basis; half the staff is assigned to work from home, and then they rotate.

“It’s decreased the actual number of people, our footprint of people, here. So it’s actually a bit quiet, but I wasn’t going to stop seeing patients because I felt that wasn’t the right thing to do,” says McAllister.

Hutchinson has made similar changes to care delivery for migraine patients.

“We’re encouraging everyone to do a virtual follow-up,” says Hutchinson. “We do allow people to come in … if they’re not doing well, and some people come in for a nerve block. … We also still have patients that come in every 12 weeks for Botox for their chronic migraine.”

Communication with migraine patients is also important in delivering quality care during the pandemic. At Kolvita Family Medical Group, Davis and her staff send out weekly emails with COVID-19 updates to patients.

“We get a nice response when we send out our emails because they’re pretty objective and informative. We’ll get responses saying, ‘Thank you. It’s always so calming to hear from you guys and get some real information,’ even though we’re very clear that we don’t have all of the answers and that the testing is not as accurate as we would hope it would be,” Davis says.

The continued uncertainty around when the pandemic will come to an “end” can be particularly difficult for migraine patients who like structure.

“It’s going to be a process though, right? There’s still going to be a little stress as things open up because you have that uneasiness of, ‘Is it safe?’ It’s the new normal, so I think it’ll be gradual, but yes, some people’s migraines will get better as they feel more comfortable getting back to some degree of normalcy,” says Hutchinson.

Until then, communicating with migraine patients is important. The pandemic continues to evolve, and new information is released nearly every day — but there is also a lot of misinformation that can make it hard for patients to decipher fact from fiction.

“Our weekly emails have been huge,” says Davis. “Sometimes it’s hard to be super proactive, but that persistent reminder that they need to not disregard other aspects of their health care is very important. The persistent reminder that we’re still here, even if it’s not physically in the office, we have access by phone and technology. That constant ‘Please reach out to us if you have questions and concerns on any of your health care issues’ is hugely important.”

If the only communication to the patient base is telling them about the office’s COVID-19 protocols, patients may get the impression that their physician is only focusing on COVID-19 and not on other important health concerns, including migraine.

Says Davis: “I think (if you have) some method (to communicate) — whether it’s on your website or if you have a social media platform that your patients look at or you have the ability to mass message them — (you) should.”
Align with the guidelines for patients at risk

**XIFAXAN was given the highest possible recommendation by AASLD/EASL**

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

**GRADE I:** Proven in randomized, controlled trials¹

**GRADE A:** Evidence is “high quality,” and further research is very unlikely to change our confidence in the estimated effect¹

**GRADE 1:** Recommendation is “strong,” with factors influencing strength of recommendation including the quality of evidence, presumed patient-important outcomes, and costs¹

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**References:**
XIFAXAN cut the risk of OHE recurrence and HE-related hospitalizations in half²

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

**Study design**²,³

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

**INDICATION**

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

**IMPORTANT SAFETY INFORMATION**

- XIFAXAN is contraindicated in patients with a hypersensitivity to rifaximin, rifamycin antimicrobial agents, or any of the components in XIFAXAN. Hypersensitivity reactions have included exfoliative dermatitis, angioneurotic edema, and anaphylaxis.
- *Clostridium difficile*-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including XIFAXAN, and may range in severity from mild diarrhea to fatal colitis. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued.
- There is an increased systemic exposure in patients with severe (Child-Pugh Class C) hepatic impairment. Caution should be exercised when administering XIFAXAN to these patients.
- Caution should be exercised when concomitant use of XIFAXAN and P-glycoprotein (P-gp) and/or OATPs inhibitors is needed. Concomitant administration of cyclosporine, an inhibitor of P-gp and OATPs, significantly increased the systemic exposure of rifaximin. In patients with hepatic impairment, a potential additive effect of reduced metabolism and concomitant P-gp inhibitors may further increase the systemic exposure to rifaximin.
- In a clinical study, the most common adverse reactions for XIFAXAN in HE (≥10%) were peripheral edema (15%), nausea (14%), dizziness (13%), fatigue (12%), and ascites (11%).
- INR changes have been reported in patients receiving rifaximin and warfarin concomitantly. Monitor INR and prothrombin time. Dose adjustment of warfarin may be required.
- XIFAXAN may cause fetal harm. Advise pregnant women of the potential risk to a fetus.

To report SUSPECTED ADVERSE REACTIONS, contact Salix Pharmaceuticals at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
5.5 Concomitant Use with P-glycoprotein Inhibitors

5.2 Clostridium difficile

2.4 Administration

XIFAXAN can be taken with or without food.

4. CONTRAINDICATIONS

XIFAXAN is contraindicated in patients with a hypersensitivity to rifaximin, any of the rifamycins, antimicrobial agents, or any of the excipients of XIFAXAN. Hypersensitivity reactions, including exfoliative dermatitis, angioedema, and anaphylaxis, have been reported with XIFAXAN.

5. WARNINGS AND PRECAUTIONS

5.2 Clostridium difficile-Associated Diarrhea

Clostridium difficile-associated diarrhea (CDAD) has been reported with nearly all anti-infective agents, including XIFAXAN, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon which may lead to overgrowth of C. difficile. C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxic strains of C. difficile cause increased morbidity and mortality, as these infections are typically acquired in healthcare settings and are often associated with significant mortality. The severity of clinical illness ranges from mild to life-threatening. Severe perforative colitis and death may occur if not treated promptly. Trimethoprim-sulfamethoxazole and quinolones are important causes of CDAD.

7.2 Warner

Changes in INR have been reported postmarketing in patients receiving rifaximin and warfarin concurrently. Monitor INR and prothrombin time. Dose adjustment of warfarin may be needed to maintain target INR range. See prescribing information for warfarin.

7.3 CYP3A4 Substrates

An in-vitro study has suggested that rifaximin induces CYP3A4. However, in patients with normal liver function, rifaximin at the recommended dosing regimen is not expected to induce CYP3A4. It is unknown whether rifaximin can have a significant effect on the pharmacokinetics of concomitant CYP3A4 substrates in patients with reduced liver function who have elevated rifaximin concentrations.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

There are no available data on rifaximin use in pregnant women to inform any drug-associated changes in the systemic exposure of rifaximin. Caution should be exercised when concomitant use of XIFAXAN and a P-gp inhibitor such as cyclosporine is considered because rifaximin is a P-gp substrate. A potential additive effect of reduced metabolism and concurrent P-gp inhibitors may further increase the systemic exposure to rifaximin.

6 ADVERSE REACTIONS

6.1 Clinical Studies Experience

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

6.2 Postmarketing Experience

The safety and effectiveness of XIFAXAN has not been established in children less than 18 years of age.

7.2 Warner

Changes in INR have been reported postmarketing in patients receiving rifaximin and warfarin concurrently. Monitor INR and prothrombin time. Dose adjustment of warfarin may be needed to maintain target INR range. See prescribing information for warfarin.

7.3 CYP3A4 Substrates

An in-vitro study has suggested that rifaximin induces CYP3A4. However, in patients with normal liver function, rifaximin at the recommended dosing regimen is not expected to induce CYP3A4. It is unknown whether rifaximin can have a significant effect on the pharmacokinetics of concomitant CYP3A4 substrates in patients with reduced liver function who have elevated rifaximin concentrations.

*Table 1: Most Common Adverse Reactions* in HE Trial

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Abdominal pain</em></td>
<td>3%</td>
</tr>
<tr>
<td><em>Diarrhea</em></td>
<td>2%</td>
</tr>
<tr>
<td><em>Flatulence</em></td>
<td>2%</td>
</tr>
</tbody>
</table>

Approximately 1.8 times the recommended dose for TD (550 mg per day) and approximately 2.6 times the recommended dose for HE (1100 mg per day) observed in the clinical trial (n=140) and in a long term follow-up study (n=280).

On the basis of studies on 6- and 8-month placebo-controlled clinical trials (n=198) and in a long term follow-up study (n=280). The proportion of patients with an increase in ALT or AST of ≥ 2.5 times normal was 3% to 4% in each of the 6- and 8-month placebo-controlled clinical trials (n=198) and in the long term follow-up study (n=280). On the basis of studies on 4- and 6-month placebo-controlled clinical trials (n=198) and in the long term follow-up study (n=280). Approximately 0.9% to 1.8 times the recommended dose for TD (550 mg per day) and approximately 2.6 times the recommended dose for HE (1100 mg per day) observed in the clinical trial (n=140) and in a long term follow-up study (n=280).

On the basis of studies on 6- and 8-month placebo-controlled clinical trials (n=198) and in the long term follow-up study (n=280). Approximately 0.9% to 1.8 times the recommended dose for TD (550 mg per day) and approximately 2.6 times the recommended dose for HE (1100 mg per day) observed in the clinical trial (n=140) and in a long term follow-up study (n=280).
Coding case studies

Migraine

by Renee Dowling, CPC Contributing Author

Getting paid requires accurate documentation and correct code selection. In our coding case studies, we explore the correct coding for a specific condition based on a hypothetical clinical scenario. This particular scenario involves a patient presenting with symptoms of migraine. See if you can choose the correct codes.

Clinical Scenario

Chief complaint
Patient is a 44-year-old woman who presents via phone today for follow-up of migraine headaches and nausea.

Patient’s location: home
Patient verbally consents and authorizes the physician to provide and perform care as considered advisable for the patient’s health and well-being. This encounter is conducted via a telephone visit.

Provider location: provider’s home

History of present illness
- Last office visit was Oct. 15, 2020, with her primary care physician for adult attention-deficit/hyperactivity disorder (ADHD). She was prescribed Adderall 20 mg twice per day.
- Her last fill of Adderall was Sept. 24, 2020, for quantity 60, and she has not refilled since her last office visit.
- Patient was referred to pain management and had her first visit.
- Patient is requesting refills on Adderall, meclizine, Phenergan and Imitrex.
- All medications the patient is requesting have a refill already waiting on her at the pharmacy.
- She reports taking Adderall 20 mg daily, meclizine 1-2 times daily, Phenergan 2-6 tablets daily and Imitrex nasal spray twice daily.

Review of systems
- Constitutional: negative for chills, fatigue and fever.
- Head, ears, nose, throat: negative for sore throat.
- Respiratory: negative for cough and shortness of breath.
- Cardiovascular: negative for chest pain and leg swelling.
- Gastrointestinal: negative for abdominal pain, nausea and vomiting.
- Genitourinary: negative for difficulty urinating.
- Neurological: negative for dizziness, lightheadedness and headaches.

Physical exam
- Not applicable: telehealth visit.

Assessment and plan

Migraine without status migrainosus, not intractable, unspecified migraine type
- Stable, refill sent to pharmacy. Patient needs to follow up with primary care physician in one month to continue this medication.
- Sumatriptan (Imitrex) 20 mg actuation nasal spray; administer one spray (20 mg total) by nasal route as needed for one dose for migraine. Maximum two doses per day.
- Dispense six inhalers with zero refills.

Nausea
- Stable, refill sent to pharmacy. Patient needs to follow up with primary care physician in one month to continue this medication.
- Promethazine (Phenergan) 25 mg tablet; take one tablet (25 mg total) by mouth every six hours as needed for nausea.
- Dispense 90 tablets with zero refills.
- Meclizine (Antivert) 25 mg tablet; take one tablet (25 mg total) by mouth three times daily as needed for dizziness or nausea.
- Dispense 90 tablets with zero refills.

Adult ADHD
- Stable, refill sent to pharmacy. Patient needs to follow up with primary care physician in one month to continue this medication.
- Dextroamphetamine-amphetamine (Adderall) 20 mg tablet, take one tablet (20 mg total) by mouth every morning.
- Dispense 30 tablets with zero refills.
Documentation Coding Requirements
When documenting a migraine include the following:

**Type:**
- Hemiplegic.
- Persistent migraine aura.
- Chronic.
- Ophthalmoplegic.
- Periodic headache syndrome.
- Abdominal.
- Menstrual.
- Other.

**With or without:**
- Aura.
- Cerebral infarction.
- Status migrainosus
- Cyclical vomiting.

**Intractable or not intractable.**

Additional coding guidance for G43 category: Use additional code for adverse effect, if applicable, to identify drug (T36-T50 with fifth or sixth character 5).

**Migraine ICD-10 codes**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>G43.001</td>
<td>Migraine without aura, not intractable, with status migrainosus</td>
</tr>
<tr>
<td>G43.009</td>
<td>Migraine without aura, not intractable, without status migrainosus</td>
</tr>
<tr>
<td>G43.011</td>
<td>Migraine without aura, intractable, with status migrainosus</td>
</tr>
<tr>
<td>G43.019</td>
<td>Migraine without aura, intractable, without status migrainosus</td>
</tr>
<tr>
<td>G43.101</td>
<td>Migraine with aura, not intractable, with status migrainosus</td>
</tr>
<tr>
<td>G43.109</td>
<td>Migraine with aura, not intractable, without status migrainosus</td>
</tr>
<tr>
<td>G43.119</td>
<td>Migraine with aura, intractable, with status migrainosus</td>
</tr>
<tr>
<td>G43.401</td>
<td>Hemiplegic migraine, not intractable, with status migrainosus</td>
</tr>
<tr>
<td>G43.409</td>
<td>Hemiplegic migraine, not intractable, without status migrainosus</td>
</tr>
<tr>
<td>G43.411</td>
<td>Hemiplegic migraine, intractable, with status migrainosus</td>
</tr>
<tr>
<td>G43.419</td>
<td>Hemiplegic migraine, intractable, without status migrainosus</td>
</tr>
<tr>
<td>G43.501</td>
<td>Persistent migraine aura without cerebral infarction, not intractable, with status migrainosus</td>
</tr>
<tr>
<td>G43.509</td>
<td>Persistent migraine aura without cerebral infarction, not intractable, without status migrainosus</td>
</tr>
<tr>
<td>G43.511</td>
<td>Persistent migraine aura without cerebral infarction, intractable, with status migrainosus</td>
</tr>
<tr>
<td>G43.519</td>
<td>Persistent migraine aura without cerebral infarction, intractable, without status migrainosus</td>
</tr>
<tr>
<td>G43.601</td>
<td>Persistent migraine aura with cerebral infarction, not intractable, with status migrainosus</td>
</tr>
<tr>
<td>G43.609</td>
<td>Persistent migraine aura with cerebral infarction, not intractable, without status migrainosus</td>
</tr>
<tr>
<td>G43.611</td>
<td>Persistent migraine aura with cerebral infarction, intractable, with status migrainosus</td>
</tr>
<tr>
<td>G43.619</td>
<td>Persistent migraine aura with cerebral infarction, intractable, without status migrainosus</td>
</tr>
<tr>
<td>G43.701</td>
<td>Chronic migraine without aura, not intractable, with status migrainosus</td>
</tr>
<tr>
<td>G43.709</td>
<td>Chronic migraine without aura, not intractable, without status migrainosus</td>
</tr>
<tr>
<td>G43.711</td>
<td>Chronic migraine without aura, intractable, with status migrainosus</td>
</tr>
<tr>
<td>G43.719</td>
<td>Chronic migraine without aura, intractable, without status migrainosus</td>
</tr>
<tr>
<td>G43.A0</td>
<td>Cyclical vomiting, not intractable</td>
</tr>
<tr>
<td>G43.A1</td>
<td>Cyclical vomiting, intractable</td>
</tr>
<tr>
<td>G43.B0</td>
<td>Ophthalmoplegic migraine, not intractable</td>
</tr>
<tr>
<td>G43.B1</td>
<td>Ophthalmoplegic migraine, intractable</td>
</tr>
<tr>
<td>G43.C0</td>
<td>Periodic headache syndromes in child or adult, not intractable</td>
</tr>
<tr>
<td>G43.C1</td>
<td>Periodic headache syndromes in child or adult, intractable</td>
</tr>
<tr>
<td>G43.D0</td>
<td>Abdominal migraine, not intractable</td>
</tr>
<tr>
<td>G43.D1</td>
<td>Abdominal migraine, intractable</td>
</tr>
</tbody>
</table>

**DIAGNOSIS CODE**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>G43.909</td>
<td>Migraine, unspecified, not intractable, without status migrainosus</td>
</tr>
<tr>
<td>R11.0</td>
<td>Nausea</td>
</tr>
<tr>
<td>F90.9</td>
<td>Attention-deficit/hyperactivity disorder, unspecified type</td>
</tr>
</tbody>
</table>

**Coding notes**
- Also code any associated seizure (G40.-, R56.9).
- Also code the type of cerebral infarction (I63.-).
- For cyclical vomiting not related to migraine, use K31.89 along with a code from category R11.
- Also code any associated premenstrual tension syndrome (N94.3).

**MORE ONLINE:**
For the full list of codes go to the February 2021 issue on MedicalEconomics.com

Renee Dowling is a billing and coding consultant with VEI Consulting in Indianapolis, Indianapolis. Send your diagnosis coding questions to medec@mjhlifesciences.com
Things You Should Know About Blood-Based Cancer Detection

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

Learning Objectives
Upon successful completion of this activity, you should be better prepared to:
• Discuss the potential role of blood testing in detecting cancer in the primary care setting, including appropriate patient selection
• Review biomarkers targeted by blood testing in cancer detection

Accreditation/Credit Designation
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Instructions for Participation/How to Receive Credit
1. Read this activity in its entirety.
2. Go to gotoper.com/go/cancerdetection2021/print 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.

To learn more about this topic, including information on current and investigational approaches to cancer screening in primary care, go to gotoper.com/online-cme-activities/cpc/cpc-fmx-cancerdetection2020
Primary care providers play a central role in identifying cancer, including screening, diagnosing and referring patients to specialists for follow-up. However, in recent years, rates of screening for several cancer types failed to reach the Healthy People 2020 targets. To address barriers in cancer screening, several blood-based multicancer detection assays are currently being investigated in clinical trials. Here are 3 things you should know about current and emerging blood-based strategies for identifying patients with cancer.

Provider and patient barriers often impede cancer screening.

Detecting cancer in primary care is challenging. Clinicians are called upon to customize screening strategies based on patients’ specific risks. Clinicians must consider factors including family history and, in some cases, additional information such as smoking exposure for lung cancer screening and history of HPV vaccination or infection for cervical cancer screening. The demands on physician time present a substantial barrier. U.S. primary care providers would need to devote an estimated 7.4 hours per day to manage all prevention activities for a typical patient panel.

Estimated >7 h/d needed for prevention-related tasks, including cancer screening

In a study that looked at 33 primary care practices within a university health system over a 2-year period, clinicians’ rate of ordering breast cancer screening tests for eligible patients was highest at 8 AM, then fell to its lowest at 5 PM (63.7% vs 47.8%, \( P < .001 \)). Rates of colorectal cancer (CRC) screening orders fell from 36.5% at 8 AM to 23.4% at 5 PM (\( P < .001 \)).

Numerous patient-related barriers that may also limit screening acceptance include:

- Inconvenience or difficulty traveling to the screening center
- Lack of physical or economic access to health care services
- Lack of trust in health care institutions

However, patient decision aids can reduce individuals’ reluctance related to screening and improve their ability to make informed decisions that agree with their values.

Blood samples offer multiple targets for cancer screening.

To address limitations of the current approach to cancer screening — and potentially detect cancer earlier — numerous clinical trials are currently investigating blood-based assays.

Targets under investigation for assessment in blood-based cancer screening include:

- **Cell-free DNA (cfDNA)**. This marker, also called circulating tumor DNA (ctDNA) when it is related to cancer, is thought to be released from cells undergoing apoptosis and necrosis; it may also be actively secreted from cells. The concentration of ctDNA in plasma varies depending on cancer type, location and stage, but it is typically low. Screening for relevant mutations in ctDNA, particularly with early cancer, requires detecting it against a setting of cfDNA from normal cells, including white blood cells. Cell-free DNA can be evaluated for mutations, fusions and other sequence alterations and also for gene silencing modifications (ie methylation).

- **Extracellular vesicles**. These lipid membrane-coated vesicles, which are secreted by all normal cell types and tumor cells, contain proteins, nucleic acids and metabolites. Extracellular vesicles isolated from a variety of fluids have shown messenger RNA, microRNA and proteins related to multiple cancer types, suggesting their potential use as targets for blood-based cancer testing.
Protein biomarkers. Individual proteins such as prostate specific antigen are currently used in early cancer detection, and panels of protein biomarkers are undergoing clinical trial evaluation.\textsuperscript{14}

Multiomic analyses. Some investigational early cancer detection tests incorporate assessment of DNA and protein biomarkers to refine early detection performance.\textsuperscript{15}

Many trials are evaluating the utility of blood screening for cancer detection.

In a study using data from the Circulating Cell-free Genome Atlas project, blood samples from 6,689 participants with cancer, representing more than 50 cancer types, or without known cancer underwent targeted methylation analysis of cfDNA.\textsuperscript{16} For a prespecified set of cancers that account for most annual cancer deaths, including colorectal, lung, ovarian and pancreatic, sensitivity for stage I to III cancers was 67.3%. Across all cancer types, specificity ranged from 18% in stage I to 81% in stage III; for pancreatic cancer specifically, these values ranged from 63% to 75%. Across all types, specificity was 99.3%. In addition, the test identified the tissue of origin in samples with a cancer-like signal with 93% accuracy.\textsuperscript{16}

The ongoing PATHFINDER study is assessing the clinical implementation of this targeted methylation cfDNA multicancer detection test.\textsuperscript{17,18} The primary endpoints are the number and types of tests needed to reach diagnostic resolution following a “signal detected” result, and the time needed to do so. When a test provides this finding, the medical team at the enrolling site that ordered the test will coordinate the resulting diagnostic workup according to its institution’s clinical practices.

“What the multicancer early detection test report provides is a signal positive versus a signal negative result. If a signal positive result is included in the report, we see an expected organ of origin. Sometimes we see more than one potential organ of origin identified. Occasionally we see a report that indicates that an organ of origin could not be determined.”

—Tomasz M. Beer, MD

At the American Association for Cancer Research Virtual Annual Meeting II in 2020, data were presented on another genomic and epigenomic cfDNA assay that was tested using a group of patients with a CRC diagnosis and a group of controls with a negative colonoscopy screening.\textsuperscript{19} Sensitivity for stage I and stage III CRC detection was 90% and 96%, respectively, and overall specificity for CRC detection was 96.6%. This approach is being tested in the ECLIPSE study, which includes screening-eligible adults at average risk of CRC.\textsuperscript{20}

KEY REFERENCES


For a full list of references go to gotoper.com/go/cancerdetection2021print
CME POST-TEST QUESTIONS

1. Which of the following is LEAST likely to present a cancer screening barrier for clinicians?
   - A. Insufficient time later in the day
   - B. Need for risk stratification when determining patient eligibility
   - C. Patient use of screening decision aids
   - D. Patient concerns related to screening discomfort

2. All of the following represent main targets of interest in research for blood-based cancer screening tests EXCEPT?
   - A. Multiomic biomarkers
   - B. Circulating tumor DNA
   - C. Extracellular vesicles
   - D. Peptidomic patterns in serum

3. Which of the following is a recent finding from the Circulating Cell-free Genome Atlas project regarding a multicancer detection test based on methylation of cfDNA?
   - A. Equal sensitivity for detecting stage I and stage III cancer
   - B. Identification of tissue of origin in samples with a cancer-like signal with 93% accuracy
   - C. Less than 50% sensitivity in detecting pancreatic cancer
   - D. Less than 88% specificity across more than 50 cancer types

To learn more about this topic, including information on current and investigational approaches to cancer screening in primary care, go to gotoper.com/online-cme-activities/cpc/cpc-fmx-cancerdetection2020

CME Provider Contact Information
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Toll-Free: 888-949-0045 | Local: 609-378-3701 | info@gotoper.com
Things You Should Know About Shingles Vaccination

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

Learning Objectives
Upon successful completion of this activity, you should be better prepared to:
• Recognize the disease burden, cost of care and long-term sequelae associated with herpes zoster infection
• Review the administration characteristics, composition and features of available shingles vaccines
• Evaluate the efficacy data associated with available shingles vaccines

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Instructions for Participation/How to Receive Credit
1. Read this activity in its entirety.
2. Go to gotoper.com/go/fmx-shingles21-print 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.
Shingles (herpes zoster) is a painful, self-limiting rash caused by reactivation of the varicella zoster virus (VZV) from childhood chickenpox. After the initial infection, VZV remains dormant within dorsal root ganglia, and in later life, it can reactivate to cause shingles due to changes in immunity or comorbid conditions. Patients with herpes zoster lesions can transmit VZV to household contacts, causing cases of chickenpox in susceptible individuals. Furthermore, shingles can have burdensome complications. Here are 3 things you should know about the importance of shingles prevention.

1. Postherpetic neuralgia is the most common complication of shingles.

Herpes zoster is clinically manifested by a painful, blistering skin eruption in a dermatomal distribution. Approximately 25% of individuals will develop herpes zoster during their lifetime, most often at the age of 50 years or older. The aftermath of herpes zoster can be complicated by a chronic condition known as postherpetic neuralgia (PHN), which is defined as pain in the affected dermatome(s) that remains for at least 90 days after acute herpes zoster infection. The risk of developing PHN is estimated at 5% for those younger than 60 years; 10% for those between 60–69 years old; and 20% for those 80 years and older.

2. Shingles vaccination prevents herpes zoster and PHN.

Shingles vaccination reduces the risk of developing herpes zoster and PHN. The first vaccine that received United States Food and Drug Administration (FDA) approval for shingles in 2006 was a live attenuated vaccine. The live vaccine significantly reduced herpes zoster infections and PHN but was less effective in adults older than 70 years. (The efficacy of this vaccine was highest in the first year of vaccination and decreased in following years, with a limited clinical efficacy after five years). As of November 2020, the live vaccine is no longer commercially available in the United States.

In 2017, a recombinant shingles vaccine became available after positive trial results and FDA approval. Two trial investigations of the recombinant vaccine demonstrated greater than 90% efficacy against herpes zoster in all age groups. Efficacy in preventing herpes zoster was 96.6% in patients aged 50 to 59 years; 97.4% in patients aged 60 to 69 years; and 91.3% in patients 70 years and older. Efficacy decreased over time, but four years post-vaccination, the efficacy in patients older than 70 years remained at 85%.

Recombinant vaccine efficacy

- Efficacy 96.6% in patients aged 50–59
- Efficacy 97.4% in patients aged 60–69
- Efficacy 91.3% in patients aged 70+

Although the severity of PHN differs among patients, it can cause a physical, occupational and emotional burden and substantially impair quality of life. Risk factors and predictors for PHN include severe and painful herpes zoster infection, severe prodromal pain and older age. Approximately 5% of older patients continue to have PHN one year after acute herpes zoster infection. Some patients have complete resolution of symptoms after several years, but in others, pain can persist indefinitely.
Shingles vaccination is recommended for healthy adults 50 years and older.

The 2018 Advisory Committee on Immunization Practices (ACIP) guidelines recommend the recombinant vaccine for the prevention of herpes zoster and PHN for all immunocompetent adults aged 50 and older.15

Persons should get the shingles vaccine if they15:

- Are 50 years or older.
- Are uncertain whether they have had chickenpox in the past.
- Have received the earlier attenuated vaccine in the past.
- Have a history of shingles.

The vaccine is kept refrigerated at 2 degrees to 8 degrees C (35.6 degrees to 46.4 degrees F) and administered by intramuscular injection in the deltoid muscle. Healthy adults should receive two doses of the vaccine, given two to six months apart.16 More than 70% of individuals experience injection site pain following vaccination, and almost 50% report muscle pain or fatigue.17

Identifying a history of chickenpox and shingles infection is not required prior to giving the vaccine, nor is testing for the varicella antibody.15 Coinadministration of the recombinant vaccine and inactivated influenza vaccine is considered safe, and demonstrated no significant differences in immune response for either vaccine.16 However, administering concomitant vaccines at different anatomic sites is recommended.19

The recombinant vaccine is not contraindicated in immunocompromised persons; however, the ACIP does not currently recommend it. The vaccine can be given to patients taking low-dose immunosuppressive medication or anticipating immunosuppression, or those who have recovered from an immunocompromising illness.15

KEY REFERENCES


For a full list of references go to gotoper.com/go/fmx-shingles21-print
CME POST-TEST QUESTIONS

1. A 74-year-old woman returns to your office with a herpes zoster infection, after presenting several days earlier with complaints of prodromal pain in two adjacent dermatomes on her thorax.

Which of the following is the most appropriate information to share with the patient?

- A. Prodromal pain is uncommon in the majority of individuals.
- B. Lesions generally crust over after 14 days.
- C. Approximately 10% of individuals with herpes zoster develop postherpetic neuralgia.
- D. Herpes zoster is more contagious than chickenpox via direct contact with lesions or airborne transmission.

2. Which statement is true regarding efficacy of herpes zoster vaccines?

- A. The live vaccine demonstrated efficacy beyond 10 years.
- B. Efficacy for the recombinant vaccine was estimated at 82.3% in patients aged 50 to 59 years, 75% in patients aged 60 to 69 years, and 39% in patients aged 70 to 79 years.
- C. Efficacy for the recombinant vaccine was 89% overall in age groups 50 to 59 years, 60 to 69 years, and older than 70 years.
- D. Efficacy for the recombinant vaccine was 96.6% in age groups 50 to 59 years, 97.4% in patients ages 60 to 69 years, and 91.3% in patients 70 and older.

3. When discussing herpes zoster vaccination with patients aged 50 and older, which statement below is true?

- A. Administration with other vaccines is contraindicated.
- B. Serologic testing for evidence of prior varicella disease is unnecessary before administering herpes zoster vaccine.
- C. Recombinant herpes zoster vaccine is not indicated for patients who were previously administered the live vaccine.
- D. Live herpes zoster vaccine can be substituted for the second dose, if recombinant vaccine is unavailable.

To learn more about this topic, including information on complications of shingles and ACIP guidelines for vaccination, go to gotoper.com/online-cme-activities/cpc/cpc-fmx20shingles

CME Provider Contact Information
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Things You Should Know About Chronic Kidney Disease

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

Learning Objectives
Upon successful completion of this activity, you should be better prepared to:
• Identify CKD as a unique disease with a high risk of cardiovascular and renal comorbidities
• Describe recommended diagnostic practices for CKD in patients with T2D
• Evaluate the efficacy and safety of nonsteroidal mineralocorticoid receptor antagonists and other therapies under investigation for the treatment of patients with CKD

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1. Read this activity in its entirety.
2. Go to gotoper.com/go/ckd2021print to access and complete the post-test.
3. Answer the evaluation questions.
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To learn more about this topic, including information on the treatment of chronic kidney disease (CKD) in type 2 diabetes (T2D), go to gotoper.com/online-cme-activities/cpc/cpc-fmx20ckd

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Executive Director
Primary Care Metabolic Group
Los Angeles, California


This activity was written by PER® editorial staff under faculty guidance and review.

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Diabetes mellitus is the primary cause of chronic kidney disease (CKD), and despite the use of antidiabetic and antihypertensive therapies, the risk for renal complications remains high. The etiology of CKD involves renal hemodynamic changes, inflammation, ischemia and an overactive renin-angiotensin-aldosterone system (RAAS). What follows is a cascade of events ranging from hyperglycemia to renal fibrosis. Early identification of patients with Type 2 diabetes (T2D) at risk for CKD can lead to prompt treatment, with the goal of slowing down disease progression and preventing cardiovascular morbidity and mortality.

Here are 3 things you should know about the burden of CKD and emerging renoprotective strategies to treat it.

1. **CKD progression damages more than just the kidneys.**

   CKD develops in up to 40% of patients with diabetes; diabetic kidney disease is becoming the leading cause of end-stage renal disease (ESRD) in the United States. CKD also affects the development of cardiovascular disease (CVD). The interplay between the cardiovascular and renal systems can result in a complex syndrome of cardiorenal dysfunction. CKD in T2D has multiple pathophysiologic mechanisms involving both microvascular and macrovascular changes. These changes lead to albuminuria, decreased glomerular filtration or both, and are major risk factors for CVD. The combination of diabetes and CKD results in a higher risk for developing CVD, which is largely related to the presence of CKD. Patients with CKD are also more likely to die from CVD than from progression to ESRD.

   Conventional modifiable risk factors, including hyperglycemia, hyperlipidemia and hypertension, are prevalent among patients with diabetes and contribute to the heightened risk of CKD but do not fully account for it.

   Besides the metabolic and hemodynamic drivers, there are inflammatory and fibrotic drivers that lead to CKD development and progression, which current therapies do not address.

2. **Undiagnosed CKD affects nearly 50% of patients with T2D.**

   CKD is clinically defined as the presence of either kidney damage or decreased kidney function for three or more months, irrespective of cause. The Kidney Disease: Improving Global Outcomes (KDIGO) 2020 clinical practice guidelines for diabetes management in CKD recommend annual screening for CKD for all patients with T2D, beginning at the time of diagnosis. Estimated glomerular filtration rate (eGFR) and urinary albumin excretion rate need to be assessed, since evaluating either measurement alone may not capture all patients with CKD. Cutoff values for these tests are urinary albumin-to-creatinine ratio of 30 mg/g or higher and/or sustained reduction in eGFR below 60 mL/min/1.73 m².

   Only 42% of patients with diabetes received annual urine albumin screening in 2014. Furthermore, results of a recent study showed that undiagnosed CKD is present in up to 49% of patients with T2D. These data are consequential, as patients with only mild decrements in eGFR (eGFR between 60 and 89 mL/min/1.73m²) have a significantly increased risk of cardiovascular mortality, and this risk increases up to 20-fold by the time a patient needs renal replacement therapy or has ESRD.

   When screening for CKD, a spot urine sample for albumin is preferred, rather than timed or 24-hour collections; however, a spot urine test is subject to false-negative and false-positive results. Therefore, abnormal findings in two out of three spot urine specimens collected within 3-6 months should be present before diagnosing the patient with albuminuria.

3. **Novel treatments are emerging for treating CKD in T2D.**

   Providing effective drug therapy remains challenging for patients with diabetes.
and CKD. Even when glucose levels and blood pressure are controlled, certain patients with CKD still progress to ESRD. Conventional treatments manage blood glucose levels with glucose-lowering therapies and regulate blood pressure levels by RAAS inhibition. Newer renoprotective strategies target modifiable CKD risk factors and the specific stages of the pathogenetic pathways. These strategies may slow CKD progression to ESRD.

Newer antihyperglycemic agents have been investigated, including the sodium-glucose cotransporter-2 (SGLT-2) inhibitors. Post-hoc analysis of the cardiovascular outcomes trial DECLARE-TIMI 58 showed that dapagliflozin prevented and reduced the progression of kidney disease compared with placebo in patients with T2D, with or without established atherosclerotic CVD, most of whom had preserved renal function. Empagliflozin was compared against placebo in the EMPA-REG OUTCOME trial; patients with T2D, established CVD and CKD who received empagliflozin had improved clinical outcomes and reduced mortality. The CREDENCE trial was designed to assess the cardiovascular outcomes of canagliflozin. The results of that trial demonstrated a lower risk of kidney failure and cardiovascular events in patients with T2D and kidney disease, including patients with reduced eGFR at baseline, who received canagliflozin compared with placebo. Similarly, glucagon-like peptide-1 (GLP-1) analogs (liraglutide and semaglutide) improved renal outcomes in patients with T2D. Other glucose-lowering agents with specific therapeutic targets include the dipeptidyl peptidase-4 (DPP-4) inhibitors. However, the degree of renoprotection associated with DPP-4 inhibitor use is unclear. One meta-analysis reported that the use of DPP-4 inhibitors reduces the progression of albuminuria and, in general, has a neutral impact on the GFR.

Current treatments largely leave the major drivers of CKD progression, inflammation and fibrosis unaddressed. There is increasing evidence that inflammation and fibrosis might be caused by mineralocorticoid receptor overactivation in the kidney. Mineralocorticoid receptor antagonists (MRAs) have been available for more than half a century—spironolactone was the first of its kind—but steroidal MRAs are associated with adverse effects, including an increased risk of hyperkalemia. Nonsteroidal MRAs have been developed as adjunctive therapies to reduce the risks of CKD and CVD in patients with T2D. The phase 3 FIDELIO trial assessed the efficacy and safety of finerenone in patients with CKD and T2D. The results showed that treatment with finerenone resulted in a lower risk of CKD progression and cardiovascular events, compared with placebo. The ongoing FIGARO trial will determine whether an optimally treated cohort of patients with T2D and CKD, at high risk of cardiovascular and renal events, will have cardiorenal benefits with the addition of finerenone to their treatment regimen.

### EMERGING TREATMENTS FOR CKD IN T2D

<table>
<thead>
<tr>
<th>Category</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>SGLT-2 inhibitors</td>
<td>(e.g., dapagliflozin, empagliflozin)</td>
</tr>
<tr>
<td>GLP-1 analogs</td>
<td>(e.g., liraglutide and semaglutide)</td>
</tr>
<tr>
<td>DPP-4 inhibitors</td>
<td>(e.g., sitagliptin and linagliptin)</td>
</tr>
<tr>
<td>Nonsteroidal MRAs</td>
<td>(e.g., finerenone)</td>
</tr>
</tbody>
</table>

**KEY REFERENCES**


For a full list of references go to gotoper.com/go/ckd2021print
CME POST-TEST QUESTIONS

1 Which of the following is true regarding the relationship between cardiovascular disease (CVD) and chronic kidney disease (CKD)?
   A Albuminuria is a predictor of CKD but not CVD
   B CVD risk increases when the urine albumin-to-creatinine ratio exceeds 300 mg/g
   C Individuals with an eGFR between 60 and 89 mL/min/1.73m² have a significantly higher risk of developing CVD than those with a higher eGFR
   D Patients with CKD are more likely to eventually require dialysis than die from CVD

2 Which of the following is true regarding KDIGO screening guidelines for CKD in patients with type 2 diabetes (T2D)?
   A Urine albumin-to-creatinine ratio and eGFR should be assessed at diagnosis and at least annually in all patients with T2D
   B In patients with CVD, risk factors (eg, obesity, hyperlipidemia and/or hypertension), urinary albumin and eGFR should be assessed every 2 years
   C Patients who maintain a hemoglobin A1c of < 7.0% can be screened with evaluation of urinary albumin and eGFR every 5 years
   D Regardless of CVD risk factors, patients should be instructed to sporadically check for proteinuria in first morning specimens using a reagent strip device and report to their provider when >300 mg/L

3 What role could nonsteroidal mineralocorticoid receptor antagonists play in the management of patients with CKD and diabetes who are at risk for disease progression and cardiovascular complications?
   A They can activate the mineralocorticoid receptor to improve cardiac function
   B They can target modifiable hemodynamic and metabolic disease factors
   C They can target modifiable inflammatory and fibrotic drivers of disease
   D They can replace renin-angiotensin-aldosterone system inhibitors

To learn more about this topic, including information on the treatment of CKD in type 2 diabetes, go to gotoper.com/online-cme-activities/cpc/cpc-fmx20ckd
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2. **Compare the number of doses that can be safely stored during a 24 hour test period:**
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   - Tests for autonomic balance, vascular health, physical/mental stress, peripheral nerve health and other critical hidden risk factors
   - Reimburses $170/test using 3 CPT codes
   - Provides a 1 page summary up to a full 24 page comprehensive report

3. SUDOMOTOR TESTING (can be combined with ANS into 1 full system)
   - Takes 3 minutes to analyze patients’ hands and feet
   - Provides a 1 page summary report
   - Assesses peripheral nerve health (c-fiber function) and asymmetry between each hand and foot
   - Reimburses $130/test (national average)

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Medical Economics
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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 infection (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 2 placebo-controlled clinical studies (Studies 1 and 2) involving 29,305 subjects aged 50 years and older who received at least 1 dose of SHINGRIX (n = 14,645) or saline placebo (n = 14,660) administered according to a 0- and 2-month schedule. At the time of vaccination, the mean age of the population was 69 years; 7,286 (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 (26.8%), fever (20.5%), and gastrointestinal symptoms (17.3%), respectively.

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 Oldera (Total Vaccinated Cohort with 7-Day Diary Card)

<table>
<thead>
<tr>
<th></th>
<th>Aged 50-59 Years</th>
<th>Aged 60-69 Years</th>
<th>Aged ≥70 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SHINGRIX %</td>
<td>Placebo %</td>
<td>SHINGRIX %</td>
</tr>
<tr>
<td>Local Adverse Reactions</td>
<td>n=1,315</td>
<td>n=1,312</td>
<td>n=1,311</td>
</tr>
<tr>
<td>Pain</td>
<td>88.4</td>
<td>14.4</td>
<td>82.8</td>
</tr>
<tr>
<td>Pain, Grade 3</td>
<td>10.3</td>
<td>0.5</td>
<td>6.9</td>
</tr>
<tr>
<td>Redness</td>
<td>38.7</td>
<td>1.2</td>
<td>38.4</td>
</tr>
<tr>
<td>Redness, &gt;100 mm</td>
<td>2.8</td>
<td>0.0</td>
<td>2.6</td>
</tr>
<tr>
<td>Swelling</td>
<td>30.5</td>
<td>0.8</td>
<td>26.5</td>
</tr>
<tr>
<td>Swelling, &gt;100 mm</td>
<td>1.1</td>
<td>0.0</td>
<td>0.5</td>
</tr>
<tr>
<td>General Adverse Reactions</td>
<td>n=1,315</td>
<td>n=1,312</td>
<td>n=1,309</td>
</tr>
<tr>
<td>Myalgia</td>
<td>56.9</td>
<td>15.2</td>
<td>49.0</td>
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<tr>
<td>Myalgia, Grade 3</td>
<td>8.9</td>
<td>0.9</td>
<td>5.3</td>
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<tr>
<td>Fatigue</td>
<td>57.0</td>
<td>19.8</td>
<td>45.7</td>
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<td>Fatigue, Grade 3</td>
<td>8.5</td>
<td>1.8</td>
<td>5.0</td>
</tr>
<tr>
<td>Headache</td>
<td>50.6</td>
<td>21.6</td>
<td>39.6</td>
</tr>
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<td>Headache, Grade 3</td>
<td>6.0</td>
<td>1.7</td>
<td>3.7</td>
</tr>
<tr>
<td>Shivering</td>
<td>35.8</td>
<td>7.4</td>
<td>30.3</td>
</tr>
<tr>
<td>Shivering, Grade 3</td>
<td>6.8</td>
<td>0.2</td>
<td>4.5</td>
</tr>
<tr>
<td>Fever</td>
<td>27.8</td>
<td>3.0</td>
<td>23.9</td>
</tr>
<tr>
<td>Fever, Grade 3</td>
<td>0.4</td>
<td>0.2</td>
<td>0.5</td>
</tr>
<tr>
<td>GIb</td>
<td>24.3</td>
<td>10.7</td>
<td>16.7</td>
</tr>
<tr>
<td>GI, Grade 3e</td>
<td>2.1</td>
<td>0.7</td>
<td>0.9</td>
</tr>
</tbody>
</table>

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

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

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

* Placebo was a saline solution.

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

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

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

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

(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 13.8%, 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 50.5% and 32.0% of subjects who received SHINGRIX (n = 14,645) and placebo (n = 14,660), respectively (Total Vaccinated Cohort). Unsolicited adverse events that occurred in ≥1% of recipients of SHINGRIX and at a rate at least 1.5-fold higher than placebo included chills (3.5% versus 0.2%), injection site pruritus (2.2% versus 0.2%), malaise (1.7% versus 0.3%), arthralgia (1.7% versus 1.2%), nausea (1.4% versus 0.5%), and dizziness (1.2% versus 0.8%).

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

Serious Adverse Events (SAEs)

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

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

Deaths

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

Potential Immune-Mediated Diseases

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

Dosing Schedule

In an open-label clinical study, 238 subjects 50 years and older received SHINGRIX as a 0- and 2-month or 0- and 6-month schedule. 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 = 14,845), 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 gE 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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GET GUIDANCE.
REFER TO THE RECONS.

THE CDC RECOS MAY HELP YOU IDENTIFY PATIENTS FOR VACCINATION

No matter how healthy they may feel, people aged ≥50 years are at risk for shingles.1-5 That’s why CDC recommends you vaccinate immunocompetent adults 50 years and older with SHINGRIX.6,*

The CDC Recommendations may help you identify patients for vaccination and establish protocols in your practice.

To read the full CDC Recommendations, visit us at Recoshingrix.com

*ACIP recommendations adopted by CDC.
ACIP=Advisory Committee on Immunization Practices; CDC=Centers for Disease Control and Prevention.

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

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


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